Mozo Grau, S.A.
Beatriz Santos
Quality Manager
Calle Santiago López González 7
47197 Valladolid
SPAIN

May 16, 2024

Re: K233137
Trade/Device Name: Ticare Dental Implant Systems
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 15, 2024
Received: April 15, 2024

Dear Beatriz Santos:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K233137

Device Name
Ticare Dental Implant Systems

Indications for Use *(Describe)*

Ticare Dental Implant Systems are endosseous dental implants intended to be implanted in the maxilla or mandible jaw bone to serve as a union between the jaw bone and a dental prosthesis for partial or total replacement of teeth in edentulous patients. They are indicated for single-stage or two-stage procedures to support screw-retained restorations and can be used for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Small diameter (3.3mm) implants are indicated to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible and should not be used in the molar region. Ti care Osseous Quattro and InHex Quattro implants are indicated to support permanently fixed restorations.

Ticare Inhex and Osseous implants of 6 mm length are intended for use in a two-stage surgical procedure and are indicated for delayed loading to support permanently fixed restorations. These implants are indicated only for straight abutments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 05 – 510(k) SUMMARY

DATE OF SUBMISSION: 2024-05-16
SUBMITTER NAME: MOZO GRAU, S.A.
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DEVICE TRADE NAME: Ticare Dental Implant Systems

COMMON NAME: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments

REGULATION DESCRIPTION: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments

REGULATION NUMBER: 21 CRF 872.3640

REGULATION CLASS: Class II

PRIMARY PRODUCT CODE: DZE
SECONDARY PRODUCT CODE: NHA

PREDICATE DEVICE INFORMATION
Primary Predicate:

K151391 BTI Dental Implant System UnicCa®

Reference Predicates:

K142260 NobelActive®
K111216 Biomet 3i OSSEOTITE® 2 Dental Implants
K172576 Biohorizons
K142167 Medentika
K202344 Nobel Biocare AB
K022258 B.T.I. Biotechnology Institute

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K161435 Nobel Biocare AB
K192522 Biomet 3i LLC
K210220 KontactTM Dental Implant System
K990277 O-Ring Abutment System
K130999 OsseoSpeed TM Profile EV

INTENDED USE / INDICATIONS FOR USE:

The intended purpose of the subject device is:

Ticare Dental Implant System is indicated for surgical placement in the upper or lower jaw arches, for single-stage or two-stage surgical procedures and cemented, screw retained restorations or overdentures. Ticare Dental Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

The indications for use of the subject device are:

Ticare Dental Implant Systems are endosseous dental implants intended to be implanted in the maxilla or mandible jaw bone to serve as a union between the jaw bone and a dental prosthesis for partial or total replacement of teeth in edentulous patients. They are indicated for single-stage or two-stage procedures to support screw-retained restorations and can be used for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Small diameter (3.3mm) implants are indicated to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible and should not be used in the molar region. Ticare Osseous Quattro and Inhex Quattro implants are indicated to support permanently fixed restorations.

Ticare Inhex and Osseous implants of 6 mm length are intended for use in a two-stage surgical procedure and are indicated for delayed loading to support permanently fixed restorations. These implants are indicated only for straight abutments.

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DEVICE DESCRIPTION

The subject device is a dental implant system including threaded, root-form endosseous dental implants of various diameters and lengths, straight, angled, tapered, UCLA and ball abutments + retention cap as well as healing abutments, cover screws and retaining screws to secure prosthetic restorations. Implants are commercially pure Grade IV titanium except for InHex "Mini" and InHex Quattro "Mini" implants which are Grade V titanium alloy. Abutments and screws are grade V titanium alloy 6Al 4V. Retention cap is Vestakeep D4 R. All implants have an RBM surface. Abutments must be matched to implant design and platform size. Provisional and temporary abutments are for use no more than 2-3 months. Some Inhex abutment designs have a narrow neck alternative version to allow the clinician more choices for soft tissue management.

Osseous dental implants have an external hex connection and are available in three platforms, standard, mini and maxi. Mini platform comes in a diameter of 3.3mm with lengths of 10, 11.5, 13 and 15mm. Standard platform comes in diameters of 3.4, 3.75, and 4.25mm with lengths of 8, 10, 11.5, 13, 15mm (no 8mm in 3.4). There is also a 5.0 standard platform implant which comes in lengths of 6, 8, 10, 11.5, 13 and 15mm. Maxi comes in a diameter of 5.0mm and lengths of 6, 8, 10, 11.5, 13 and 15mm.

InHex dental implants have an internal hex connection and are available in three platforms, standard, mini and maxi. Mini platform comes in a diameter of 3.3mm with lengths of 10, 11.5, 13, 15mm. Standard platform comes in diameters of 3.75, and 4.25mm in lengths of 6 (not in 3.75), 8, 10, 11.5, 13 and 15mm. There is also a 5.0mm diameter implant in standard platform which only comes in a 6mm length. Maxi platform comes in a diameter of 5.0mm with lengths of 9, 10, 11.5, 13, 15mm.

The Osseous Quattro and InHex Quattro implant thread design enables them to be used in softer bone types. Osseous Quattro dental implants have an external hex connection in standard platform and are available in diameters 3.75mm and 4.25mm and lengths of 8, 10, 11.5, 13 and 15mm. InHex Quattro dental implants have an internal hex connection in mini and standard platform and are available in diameters of 3.3mm (mini platform), 3.75mm and 4.25mm and lengths 8 (not in 3.3), 10, 11.5, 13 and 15mm.

Maxi platform implants and abutments are for use in the molar region. Mini platform implants and abutments are for use in lateral incisors and lower central incisors. Standard platform implants and abutments are for use in all tooth locations.

Osseous straight abutments come in six designs. Prepable abutments come in hexed and non-hexed with a gingival height of 2mm in standard, mini, and maxi platforms. Tall straight abutments come in hexed with gingival heights of 0.5, 1, 2, 3, 4mm in standard, mini and maxi platforms. Short straight abutments come in hexed and non-hexed with gingival heights of 0.5, 1, 2, 3mm in standard and mini

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platforms. Multitask abutments comes in maxi platform and has a gingival height of 2mm. One piece abutments are non-hexed with gingival heights of 1, 2, 3, 4mm in standard, mini, and maxi platforms. Aesthetic abutments are hexed with gingival heights of 3 or 4mm in standard platform.

Inhex straight abutments come in six designs. Prepable abutments come in hexed and non-hexed (not in mini) with a gingival height of 2mm in standard, mini, and maxi platforms. There is an additional hexed standard platform prepable abutment with a smooth exterior for cementing. Tall straight abutments come in hexed and non-hexed with gingival heights of 0.5, 1, 2, 3, 4mm (4mm not in mini) in standard, mini and maxi platforms. There are also tall abutments with smooth surfaces for 5.0 implants which come in gingival heights of 3 or 4mm for both standard and maxi platforms. Short straight abutments come in hexed and non-hexed with gingival heights of 0.5, 1, 2, 3mm in standard, mini and maxi platforms. Multitask abutments comes in standard and maxi platform and has a gingival height of 2mm. One piece abutments are non-hexed with gingival heights of 1, 2, 3, 4mm in standard and maxi platforms. Aesthetic abutments are hexed with gingival heights of 3 or 4mm in standard and maxi platform. Inhex narrow neck tall straight abutments hexed and non-hexed come in mini platform with gingival heights of 2, 3mm and maxi & standard platforms with gingival heights of 2, 3, 4mm. Narrow neck short straight abutments hexed and non-hexed come in mini platform with gingival heights of 2, 3m and maxi & standard platforms with gingival heights of 2, 3, 4mm.

Osseous healing screws come in gingival heights of 2, 3, 4, 5, 6, 7mm (no 2mm in mini) in standard, mini, and maxi platforms. Osseous aesthetic healing screws come in gingival heights of 3, 4, 5, 6, 7mm in standard and maxi platforms. There is an additional model in standard platform which has a tapered seating area.

Inhex healing screws come in gingival heights of 1, 2, 3, 4, 5, 6, 7mm (no 1mm in maxi) in standard and maxi platform. Inhex mini platform healing screws come in gingival heights of 3 or 4mm.There is an additional shorter design of healing screw for 5.0mm implants in gingival heights of 3, 4, 5, 6, 7mm in standard and maxi platform. Inhex aesthetic healing screws come in gingival heights of 3, 4, 5, 6, 7mm in standard and maxi platforms. Narrow neck healing screws come in mini platform with gingival heights of 2, 3, 4mm and maxi & standard platform with gingival heights of 2, 3, 4, 5mm.

Osseous angled abutments come in 15° and 20° in standard, maxi, and mini platforms.

Inhex angled abutments come in 15° and 20° in gingival heights of 1, 3, 5mm for standard and maxi platforms and gingival height of 2mm for mini platform. For 5mm implants there is also a shouldered design of 15° and 20° abutment in gingival heights of 1, 3, 5mm for standard and maxi platforms.

Osseous UCLA come in hexed and non-hexed in models for casting temporary or permanent abutments in standard, maxi and mini platforms. Osseous UCLA are for casting straight abutments with a minimum height of 4mm above the gingival collar and with a post height of no more than 9mm. The wall thickness of cast abutments should be at least 0.6mm. The angulation, wall thickness,

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and diameter of the gingival collar portion are not intended to be modified.

Inhex UCLA come in hexed and non-hexed in models for casting temporary or permanent abutments in standard, and maxi platforms. Inhex UCLA are for casting straight abutments with a minimum height of 4mm above the gingival collar and with a post height of no more than 9mm. The wall thickness of cast abutments should be at least 0.6mm. The angulation, wall thickness, and diameter of the portion from the gingival collar portion to the bottom of the UCLA are not intended to be modified.

Osseous ball attachments in standard, maxi and mini platforms come in gingival heights of 1, 2, 3, 4, 5.5mm (no 1mm in maxi or mini). The retention cap made of Vestakeep D4 R allows implants to be placed off vertical by no more than 10°. Ball attachments are for multiple restorations only.

Inhex ball attachments in standard and maxi platforms come in gingival heights of 1, 2, 3, 4, 5.5mm. The retention cap made of Vestakeep D4 R allows implants to be placed off vertical by no more than 10°. Ball attachments are for multiple restorations only.

Osseous tapered abutments come in six different cone configurations on the top. 10° tapered abutments come in standard platform gingival heights of 2, 3, 4, 5mm with cone type 2, mini platform gingival heights 3, 4, 5mm cone type 1 and maxi platform gingival heights of 2, 3, 4, 5mm with cone type 3. 30° tapered abutments come in gingival heights of 4 or 5mm in standard platform with cone type 4 and maxi platform with cone type 5. Straight tapered abutments come in standard platform with cone type 6 in gingival heights of 2, 3, 4, 5mm. Angled tapered abutments come in standard platform with cone type 6 with 17° in gingival heights 2, 3, 4mm and 30° in gingival heights 3, 4, 5mm. Tapered abutments are for multiple restorations only and for implants which diverge from the occlusion axis by no more than 30°.

Inhex tapered abutments come in five of the possible six cone configurations. 10° tapered abutments come in standard platform gingival heights 0, 1, 2, 3, 4, 5mm in cone type 2 and mini platform gingival heights 1, 2, 3mm in cone type 1. 10° tapered non-hexed abutments come in maxi platform gingival heights 0, 1, 2, 3, 4, 5mm in cone type 2. 30° tapered abutments in cone type 4 gingival heights 1, 2, 3, 4, 5mm come in standard platform and non-hexed maxi platform. Straight tapered abutments in cone type 6 with gingival heights 2, 3, 4, 5mm come in standard and maxi platform. Angled tapered abutments with cone type 6 come in standard and maxi platform with 17° in gingival heights of 2, 3, 4mm and 30° in gingival heights 3, 4, 5mm. Narrow neck 10° tapered abutments come in mini platform with gingival heights of 2, 3mm and standard platform with gingival heights of 2, 3, 4, 5mm. Narrow neck 10° tapered abutments non-hexed come in maxi platform with gingival heights of 2, 3, 4, 5mm. Narrow neck 30° tapered abutments come in standard platform with gingival heights of 2, 3, 4, 5mm. Narrow neck 30° tapered abutments non-hexed come in maxi platform with gingival heights of 2, 3, 4, 5mm. Tapered abutments are for multiple restorations only and for implants which

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diverge from the occlusion axis by no more than 30°.

Healing abutments for tapered abutments include ones for 10° tapered abutment in standard and maxi platforms which is used with both Osseous and Inhex, angled tapered abutments for Osseous and Inhex, and 30° angled tapered abutment specific ones which fit Osseous maxi platform or Osseous standard and Inhex standard & maxi platforms.

Covers for provisional restoration of tapered abutments come in designs for 10° tapered abutments for Osseous and Inhex, mini and standard platform specific designs for 10° tapered abutments for Osseous and Inhex, and a design for 30° angled tapered abutments for Osseous and Inhex.

Posts for use with tapered abutments come in temporary and permanent restoration versions. Temporary ones come in standard and maxi platform versions for 10° and 30° tapered abutments which can be used with Osseous or Inhex. A temporary restoration post is also available for angled tapered abutments of Osseous or Inhex and an Osseous specific mini platform for 10° tapered abutments. Posts for permanent restoration come in versions for angled tapered abutments used for Osseous and Inhex, 10° tapered abutments used for Osseous and Inhex in standard platform, 30° tapered abutments used for Osseous and Inhex in maxi and standard platforms, non-hexed for 10° tapered abutments used for Osseous and Inhex in maxi platform, and non-hexed for 10° tapered abutment for Osseous mini platform. Titanium interfaces (shorter posts) are available for 10° and 30° tapered abutments for Osseous and Inhex, angled tapered abutments for Osseous and Inhex and 10° tapered abutments for Osseous mini platform.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:
In the establishment of substantial equivalence, Ticare Osseous and InHex Dental Implant Systems are compared with the following previously cleared devices:

Primary Predicate:
BTI Dental Implant System UnicCa® (K151391)
Reference Predicates:
NobelActive® (K142260)
OSSEOTITE® Dental Implants (K111216)
BioHorizons Implant Systems (K172576)
Medentika GmbH (K142167)
Nobel Biocare AB (K202344)

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B.T.I. Biotechnology Institute (K022258)
Nobel Biocare AB (K161435)
Biomet 3i LLC (K192522)
K210220 KontactTM Dental Implant System
K990277 O-Ring Abutment System
K130999 OsseoSpeed TM Profile EV

The intended use of the subject and the predicate devices are compared in the following table:

PRODUCT	INDICATION FOR USE	EQUIVALENCE
Ticare Dental Implant Systems	Ticare Dental Implant Systems are endosseous dental implants intended to be implanted in the maxilla or mandible jaw bone to serve as a union between the jaw bone and a dental prosthesis for partial or total replacement of teeth in edentulous patients. They are indicated for single-stage or two-stage procedures to support screw-retained restorations and can be used for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Small diameter (3.3mm) implants are indicated to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible and should not be used in the molar region. Ticare Osseous Quattro and Inhex Quattro implants are indicated to support permanently fixed restorations. Ticare Inhex and Osseous implants of 6 mm length are intended for use in a two-stage surgical procedure and are indicated for delayed loading to support permanently fixed restorations. These implants are indicated only for straight abutments.	(Subject device)

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PRIMARY PREDICATE BTI Dental Implant System UnicCa® K151391	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the **partial or total replacement of teeth in edentulate patients**. Once attached to the bone, the implants act as an **anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function**. In the case of **5.5 – 6.5mm long UnicCa® implants** should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of **Tiny® 3.0 UnicCa® implants: These implants** shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.	**Equivalent** The indications for use of the subject device are aligned with the indications for use of the primary predicate, including the indications for shorter implants (e.g. 6mm length) and small diameter implants (e.g. 3.3mm).
REFERENCE PREDICATE NobelActive® **K142260**	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for single unit restorations only.	**Equivalent** Indications for use of the subject device are aligned with the indication of the predicate devices.
REFERENCE PREDICATE OSSEOTITE®	BIOMET 3i dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restoration and in partially or fully	**Equivalent** Indications for use of the subject device are

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Dental Implants **K111216**	edentulous spans with multiple single teeth utilizing delayed or immediate loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. *OSSEOTITE® 2 Dental Implants* are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.	aligned with the indication of the predicate devices.
REFERENCE PREDICATE BioHorizons Tapered Short Implants **K172576**	BioHorizons Tapered Short Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The implants may be restored using delayed loading, or with a terminal or intermediate abutment for fixed or removable bridgework, and for overdentures.	**Similar** The general indications for use of this reference predicate are similar to those of the subject device. Specific features of this reference predicate (tapered short implants) are similar to a subset of specific references within the subject device family.
REFERENCE PREDICATE Medentika Abutment System **K142167**	Medentika abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Abutments are compatible with the following implant systems: Nobel Biocare Replace Select E -Series 3.5, 4.3, 5.0, 6.0 Nobel Biocare NobelActive F -Series 3.5, 4.3, 5.0 Biomet 3i Osseotite® Certain H -Series 3.25, 4.0, 5.0 Biomet 3i Osseotite I -Series 3.25, 3.75, 4.0, 5.0 Nobel Biocare Branemark K -Series 3.3, 3.75, 4.0, 5.0 Straumann Bone Level L -Series 3.3, 4.1, 4.8 Straumann Standard N -Series 3.3, 4.1, 4.8 Zimmer Tapered Screw-vent R -Series 3.3 3.7, 4.1, 4.7, 6.0	**Similar** The general indications for use of this reference predicate are similar to those of the abutments included in the subject device. Specific features of this reference predicate (tapered abutments) are similar to a subset of specific abutment references within the subject device family.

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	Astra Tech OsseoSpeed S -Series 3.5, 4.0, 4.5, 5.0 Dentsply Friadent Frialit/Xive T -Series 3.4, 3.8, 4.5, 5.5 Dentsply Friadent Ankylos Y -Series 3.5, 4.5, 5.5, 7.0	
REFERENCE PREDICATE Kontact™ Dental Implant System **K210220**	KontactTM Dental Implant System is indicated for use in partially or fully endentulous patients to support maxillary or mandibular single unit, multiple-unit, or overdenture dental restorations. KontactTM Dental Implant System is indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate.	**Similar** The general indications for use of this reference predicate are similar to those of the abutments included in the subject device
REFERENCE PREDICATE TiUltra Implants and Xeal Abutments **K202344**	**NobelActive TiUltra** NobelActive TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive TiUltra implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive TiUltra 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Nobel Active TiUltra 3.0 implants are indicated for single-unit restorations only. **NobelReplace CC TiUltra** NobelReplace CC TiUltra implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth,	**Equivalent** Indications for use of the subject device are aligned with the indication of this reference predicate device. Specific features of this reference predicate (Inhex abutments with diameters ranging from 3mm to 7mm and posts with tapered abutments with wide diameters, 4.8mm) are similar to a subset of specific abutment references within the subject device family.

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	in order to restore patient esthetics and chewing function. The NobelReplace CC TiUltra implants are indicated for single or multiple unit restorations. The NobelReplace CC TiUltra implants can be used in splinted or non-splinted applications. The NobelReplace CC TiUltra implant may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied. **NobelParallel CC TiUltra** NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function. NobelParallel CC TiUltra implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants with <7 mm length are for delayed loading only when appropriate stability has been achieved.	
REFERENCE PREDICATE BTI Dental Implant System **K022258**	Dental implant system comprising endosseous titanium implants and prosthetic elements to be attached to the implants, as well as auxiliary elements for surgical and prosthetic procedures. The intended use of the system is the restoration of missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.	**Similar** The general indications for use of this reference predicate are similar to those of the subject device. Specific features of this reference predicate (post with tapered abutments for diameters up to 4.1mm) are similar to a subset of specific abutment

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		references within the subject device family.
REFERENCE PREDICATE Temporary Snap Abutment **K161435**	The Temporary Snap Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Temporary Snap Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Temporary Snap Abutment is not to exceed one hundred and eighty (180) days.	**Similar** The general indications for use of this reference predicate are similar to those of the subject device. Specific features of this reference predicate are similar to a subset of specific abutment references within the subject device family (UCLA abutments with diameters from 4.5mm to 6 mm).
REFERENCE PREDICATE TSV BellaTek® Express and BellaTek® Flex Abutments **K192522**	TSV BellaTek® Express and BellaTek® Flex Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained. All digitally designed superstructures and/or hybrid abutment crowns for use with TSV BellaTek Express or BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.	**Similar** The general indications for use of this reference predicate are similar to those of the subject device. Specific features of this reference predicate are similar to a subset of specific abutment references within the subject device family (Osseous abutments with diameters from 3.4mm to 6 mm).
REFERENCE PREDICATE OsseoSpeedTM Profile EV **K130999**	Implants: The ASTRA TECH Implant System - OsseoSpeed Profile EV implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: * replacing missing teeth in single or multiple unit applications in the mandible or maxilla. * immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge	**Similar** The general indications for use of this reference predicate are similar to those of the subject device. Specific features of this reference predicate are similar to a subset of specific abutment references

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	* especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective * immediate and early loading for all indications * together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate * only together with Profile EV components, Implant Driver Profile EV, Radiographic Implant Guides Profile EV and non-Indexed prosthetic components Abutments: ASTRA TECH Inriplant SyStemTM - OsseoSpeedTm EV abutments are intended to be used in conjunction with ASTRA TECH Implant SystemTrM - OsseoSpeedTM EV in fully edentulous or partially edentulous maxillary and/or mandibular arches. The ATLANTISTM Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	within the subject device family (UCLA abutments with diameters from 3.4mm to 4.5 mm).
REFERENCE PREDICATE O-Ring Abutment System **K990277**	The BioHorizons O-Ring Abutment System is intended to provide a direct a direct attachment for tissue-supported overdentures retained by two or more implants with up to a 10-degree divergence.	**Similar** The general indications for use of this reference predicate are similar to those of the abutments included in the subject device

Table 05.01 Comparison of Intended Uses

The comparison of the subject device with the primary predicate device is summarized in the following table:

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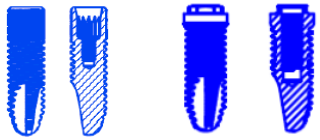
	TICARE DENTAL IMPLANT SYSTEM		Predicate device Primary predicate BTI Dental Implant System Unic Ca®		Equivalence Discussion
Manufacturer	Mozo Grau S.A		Biotechnology Institute, S.L		-
510 (k) Nº	Pending		K151391		-
Implant Design	 Threaded root form		 Threaded root form		**Equivalent** Both subject and predicate devices present internal and external connections with a range of specific diameters and lengths to be combined with abutments within the same system, including angled abutments, to support dental prosthetic restorations.
Restoration	Single-unit Multi-unit		Single-unit Multi-unit		**Identical**
Surgery Type	One or two stage (in particular for short implants, e.g. 6mm)		One stage and two-stage (for shorter implants, e.g., 5.5 – 6.5 mm)		**Equivalent** Generally, both options are indicated for implant placement. 2-stage procedures are indicated for shorter implants in both cases.
Connection Type	Internal and External Connection		Internal and External connection		**Equivalent** Both subject and predicate devices present internal and external connections with a range of specific diameters and lengths to be combined with abutments within the same system, including angled abutments, to support dental prosthetic restorations.
Implant Diameter Ranges (mm)	Internal 3.3, 3.75, 4.25 and 5 mm	External 3.3, 3.4, 3.75, 4.25 and 5.0	Internal 3.3 to 6.0	External 3.0 to 5.5	**Equivalent** Subject device diameters are within the range of diameters of the predicate device or larger. Larger dimeters do not represent

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		mm			worst case in terms of performance
Implant Length (mm)	Internal **Ø3.3**: L10, L11.5, L13 and L15 mm **Ø3.75**: L8, L10, L11.5, L13 and L15 **Ø4.25**: L6, L8, L10, L11.5, L13 and L15 **Ø5**: L6, L9, L10, L11.5, L13 and L15	External **Ø3.3**: L10, L11.5, L13 and L15 mm **Ø3.4**: L10, L11.5, L13 and L15 mm **Ø3.75**: L8, L10, L11.5, L13 and L15 mm **Ø4.25**: L8, L10, L11.5, L13 and L15 mm **Ø5**: L6, L8, L10, L11.5, L13 and L15	Internal 5.5 to 18 mm	External 7 to 18 mm	**Equivalent** Subject implant lengths are within the range of the predicate device for internal connection.
Straight Abutment Diameter, mm	Internal: 3.7, 4.0, 5.0, 6.0	External: 3.8, 4.0, 5.0, 6.0	Internal: 4.1, 5.0 5,5	External: 4.1, 5.0 5,5	**Equivalent** Subject straight abutment diameter are similar to the range of diameters for the predicate device.
Angled Abutment Angle	Internal: 15º and 20º	External: 15º and 20º	Internal: 17º	External: 17º	**Similar** Subject Angled abutment for single-unit restorations with maximum angulation (20º) is greater than the predicate angled abutment with maximum angulation (17º).

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Implant	Comercially pure titanium Grade IV, except InHex “Mini” and InHex Quattro “Mini” implants which are Grave V titanium alloy.	Commercially Pure titanium Grade IV	**Similar** Titanium materials meeting standard specifications are used.
Surface Treatment	R.B.M TC surface treatment	UnicCa®	**Similar** The surface treatment applied to subject and predicate devices is to achieve similar resulting surface characteristics.
Abutment	Titanium grade V	Pure Titanium	**Equivalent** Titanium materials meeting standard specifications are used.
Compatibility	Abutments are only compatible with T Implants	Abutments are only compatibles with BTI Implants	**Equivalent**
Sterilization	Implants: Delivered sterile via gamma radiation Abutments: Non-sterile	Implants: Delivered sterile via Gamma Radiation Abutments: Non-Sterile	**Equivalent**
Packaging	Implants are supplied individually packed inside a container body (vial) that maintains sterility through the use of a sealing barrier system. The container body is thermally sealed inside a blister to maintain sterility.	Unique container (vial with clamp)	**Similar** The sterile barrier and container achieve the same results.
Shelf life	5 Years	5 Years	**Equivalent**

Table 05.02 Comparison of Principle of Operation and Technological Characteristics – Primary Predicate

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	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous	Reference Predicate	Reference Predicate	Equivalence Discussion
		NobelActive®	OSSEOTITE® Dental Implants	
Manufacturer	Mozo Grau S.A	Nobel Biocare AB	BIOMET 3i	
510 (k) Nº	**Pending**	**K142260**	**K111216**	
Product Classification	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE; Endosseous dental implant	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE; Endosseous Dental implant	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE; Endosseous Dental implant	-
Implant Design	 InHex Quattro Osseous Quattro Threaded, root form	 Threaded, root form	 Threaded, root form	**Similar** In particular the thread design
Restoration	Single-unit Multi-Unit	Single-Unit	Single-Unit Multi-Unit	Identical
Surgery Type	One or two stage	One or two stage	Not available	**Identical**
Connection Type	Internal and External Connection	Internal Hex Connection	External Hexagon Connection	**Equivalent**
Implant body Diameter Ranges	Internal 3.3, 3.75, 4.25 and 5 mm External 3.3, 3.4, 3.75 4.25 and 5.0 mm	3.0, 3.5, 4.3, 5.0, and 5.5 mm	3.25, 3.75, 4.0, 5.0 and 6.0 mm	**Equivalent** Subject device diameters are within the range of the

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(mm)					diameters of the predicate devices.
Implant Length (mm)	Internal **Ø3.3**: L10, L11.5, L13 and L15 mm **Ø3.75**: L8, L10, L11.5, L13 and L15 **Ø4.25**: L6, L8, L10, L11.5, L13 and L15 **Ø5**: L6, L9, L10, L11.5, L13 and L15	External **Ø3.3**: L10, L11.5, L13 and L15 mm **Ø3.4**: L10, L11.5, L13 and L15 mm **Ø3.75**: L8, L10, L11.5, 13 and L15 mm **Ø4.25**: L8, L10, L11.5, L13 and L15 mm **Ø5**: L6, L8, L10, L11.5, L13 and L15	7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0 mm	3 mm to 15 mm	**Equivalent** Subject implant lengths are within the range of the predicate devices.
Implant material	Comercially pure titanium Grade IV, except InHex “Mini” and InHex Quattro “Mini” implants which are Grave V titanium alloy.		Commercially pure titanium	Commercially pure titanium	**Similar** The subject and the predicate devices are made of the similar raw materials meeting established standards.

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Implant design	Implant with straight side walls, with a conical core of the external thread and flat tip of the apex.	Not Available	Straight- walled implant body	**Identical**
Implant Surface Treatment	R.B.M surface treatment	TiUnite ® (oxidized surface)	Full OSSEOTITE	**Similar** Both subject and predicate devices have surface treatments to enhance osseointegration.
Abutment	Titanium grade V	Titanium	Titanium	**Identical**
Compatibility	Abutments are only compatible with Ticare Implants	The implants are Compatible with NobelBiocare Abutments	Compatible with all BIOMET 3i external Hex restorative components	**Equivalent** Compatibility with other implant systems is not claimed.
Supplied sterile	Yes	Yes	Yes	**Identical**
Sterilization	Sterilization by gamma radiation	Sterilization by gamma radiation	Sterilization by gamma radiation	**Identical**
Packaging	Implants are supplied individually packed inside a container body (vial) that maintains sterility through the use of a sealing barrier system. The container body is thermally sealed inside a blister to maintain sterility.	Packaged in a double aseptic vial system	Packaged in sterile tray with cover screw	**Similar**
Shelf life	5 years	5 years	5 years	**Identical**

Table 05.03 Comparison of Principle of Operation and Technological Characteristics – Reference Predicates

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	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous	Reference Predicate	Reference Predicate	Equivalence discussion
		TiUltra Implants and Xeal Abutments	TSV BellaTek Express and BellaTek Flex Abutments	
Manufacturer	Mozo Grau S.A.	Nobel Biocare AB	BIOMET 3i LLC	-
510 (k) Nº	Pending	K202344	K192522	-
Product Classification	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE; Endosseous dental implant	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE, NHA, PNP; Endosseous Dental Implant abutment	Device Class II Regulation No: 21 CFR 872.3640. Product code NHA; Endosseous Dental Implant abutment	-
STRAIGHT ABUTMENT				
Material	Titanium grade V	Titanium	Titanium alloy	Similar
Gingival Height	0.75mm, 1.11 mm, 1.40mm, 2mm, 3mm, 4mm	1.5mm, 3mm and 4.5 mm	2 mm, 4 mm	Similar,
Post Height	6.5 mm	6.5 mm	7 mm	Similar, the post height does not present significant differences. Post height can be modified to equivalent heights.
Diameter	3.7 mm, 4.8 mm and 6 mm	Min 3mm Max 5.5mm	3.8 mm, 5 mm and 6 mm	Similar, the dimensions do not present significant

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				differences.
Connection type	Hex and non hex	Internal, hex	External Hex	Same hex features. Internal or external connection depending on the implant to which it is to be connected.
ANGLED ABUTMENTS				
Material	Titanium grade V	Titanium	Titanium alloy	Similar
Angulation	15° and 20°	18° and 25°	15º	Similar
Gingival Height	1.8 mm	1.5mm and 3mm	2 mm, 4 mm	Similar
Post Height	6.5 mm	6.5 mm	7 mm	Similar, the length does not present significant differences.
Diameter	3.7 mm, 4.8 mm and 6 mm	Min 3mm Max 5.5mm	3.8 mm, 5 mm and 6 mm	Similar, the dimensions do not present significant differences.
Connection type	Hex	External hex	External Hex	Similar
COVER SCREW				
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy	Similar
Angulation	Straight	Straight	Straight	Similar
Gingival Height	0 mm, 1 mm	0 mm	1 mm	Same diameter as Nobelactive (3.5 mm) and Osseotite (3.4 mm and 4.1)
Diameter	2.5 mm, 3 mm, 3.4 mm, 4 mm, 4.1 mm and 5 mm	2.5 mm, 3 mm, 4 mm	3.4 mm, 4.1 mm, 5 mm, 6 mm	Same diameter as Nobelactive (3.5 mm) and Osseotite (3.4 mm and 4.1)
Connection type	Internal cone, External	Internal cone	External	Same diameter as Nobelactive (3.5 mm) and

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				Osseotite (3.4 mm and 4.1)
HEALING ABUTMENT				
Material	Titanium grade V	Titanium and peek	Titanium alloy	Similar
Angulation	Straight	Straight	Straight	Yes
Gingival Height	2 mm, 3 mm, 4 mm, 5 mm, 6 mm and 7 mm	3 mm, 4 mm, 5 mm and 7 mm	2 mm, 3 mm, 4 mm, 6 mm and 8 mm	Yes
Diameter	4.1 mm, 5 mm and 6 mm	3, 3.2, 3.5, 3.6, 3.8, 4, 4.2, 4.3, 4.5, 5.3, 5, 5.5, 6, 6.5 and 7 mm	3.4 mm, 4.1 mm, 5 mm and 6 mm	Same diameter as Osseotite (4.1 mm, 5mm and 6mm)
Connection type	Inhex	Inhex and internal conic	Internal conic	Same as Nobel Active

Table 05.04 Comparison of Principle of Operation and Technological Characteristics – Reference Predicate

BALL ABUTMENT COMPARISON

	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous	**Reference Predicate**	**Reference Predicate**	**Equivalence discussion**
		KontactTM Dental Implant System	**O-Ring Abutment System**	
Manufacturer	Mozo Grau S.A.	Biotech Dental, SAS	BioHorizons Implant System	-
510 (k) Nº	Pending	K210220	K990277	-

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Product Classification	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE; Endosseous dental implant	Device Class II Regulation No: 21 CFR 872.3640 Product code DZE, NHA; Endosseous Dental implant	Device Class II Regulation No: 21 CFR 872.3640 Product code DZE; Endosseous Dental implant	-
BALL ABUTMENT + retention cap				
Material	Ball abutment: Titanium grade V Retention cap: Elastic Polymer	Ball abutment: Titanium alloy Retention cap: Elastic Polymer	Ball abutment: Titanium alloy Retention cap: Elastic Polymer	Similar
Angulation	Straight	Straight	Straight	Similar
Gingival Height	0,73 mm, 2 mm, 3 mm, 4 mm and 5.5 mm	1mm, 2mm, 3mm, 4mm and 5 mm	1 mm, 2 mm, 3 mm, 4 mm, 5 mm and 6 mm	Similar
Post Height	3 mm	3 mm	3.5 mm	Same with Biotech Dental. Similar, the length does not present significant differences.
Diameter	3.4 mm, 4,1 mm and 5 mm	4,1 mm	3.5mm 4mm and 5mm	Same diameter as Biotech Dental (4.1mm) and BioHorizons(5mm). Similar as BioHorizons(3.5mm).
Connection type	Non Hex	Internal conic, Non Hex	External, Non Hex	Same as Biotech dental and BioHorizons.

Table 05.05 Comparison of Principle of Operation and Technological Characteristics – Reference Predicate

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TAPERED ABUTMENT COMPARISON

	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous TAPERED ABUTMENT	Reference Predicate Medentika Abutment System K142167	Equivalence discussion
Manufacturer	Mozo Grau S.A.	Medentika GmbH	-
510 (k) Nº	Pending	K142167	-
Product Classification	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE; Endosseous dental implant	Device Class II Regulation No: 21 CFR 872.3630. Product code NHA; Endosseous Dental Implant abutment	-
Material	Titanium grade V	Titanium grade V	Same
Angulation Cone 1, 2, 3, 4 and 5	Straight	Not available	Similar, the post height does not present significant differences. Post height can be modified to equivalent heights.
Angulation Cone 6	Straight, 17º, 30º	Straight	Similar, the gingival height does not present significant differences.
Gingival Height	2 mm, 3 mm, 4 mm, and 5 mm	1.5 mm, 2.5 mm, 3.5 mm and 5.5 mm	Similar, the gingival height does not present significant differences.
Post Height	2 mm	2 mm	Similar, the post height does not present significant differences.

Table 05.06 Comparison of Principle of Operation and Technological Characteristics – Tapered Abutment – Reference Predicate

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UCLA ABUTMENT COMPARISON

	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous UCLA ABUTMENT	Reference Predicate TiUltra Implants and Xeal Abutments	Reference Predicate Temporary Snap Abutment	Reference Predicate TSV BellaTek Express and BellaTek Flex Abutments	Reference Predicate B.T.I. Dental Implant System	Reference Predicate OsseoSpeed TM Profile EV	Equivalence discussion
Manufacturer	Mozo Grau S.A.	Nobel Biocare AB	Nobel Biocare AB.	Biomet 3i LLC	B.T.I. Biotechnology Institute, S.L.	Dentsply Implants	-
510 (k) Nº	Pending	K202344	K161435	K192522	K022258	K130999	-
Product Classification	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE; Endosseous dental implant	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE, NHA, PNP; Endosseous Dental Implant abutment	Device Class II Regulation No: 21 CFR 872.3630. Product code NHA, Endosseous Dental Implant abutment	Device Class II Regulation No: 21 CFR 872.3630. Product code NHA; Endosseous Dental Implant abutment	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE, Endosseous Dental Implant abutment	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE, NHA; Endosseous Dental Implant abutment	-
UCLA ABUTMENT							
Material	Titanium grade V	Titanium Alloy	Titanium	Titanium	Titanium	Titanium	Similar
Angulation	Straight	Straight	Straight	Straight	Straight	Straight	Similar
Gingival Height	1.11 mm	1.5 and 3 mm	1.2 mm, 1.5mm and 2mm	0.8 mm	1.5 mm	1 mm	Similar, the gingival height does not present significant differences

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	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous UCLA ABUTMENT	Reference Predicate TiUltra Implants and Xeal Abutments	Reference Predicate Temporary Snap Abutment	Reference Predicate TSV BellaTek Express and BellaTek Flex Abutments	Reference Predicate B.T.I. Dental Implant System	Reference Predicate OsseoSpeed TM Profile EV	Equivalence discussion
Post Height	10 mm	10 mm	12 mm	12 mm	12 mm	9 mm	Similar, the post height does not present significant differences. Post height can be modified to equivalent heights
Diameter	3.7mm, 4.8mm and 6mm	3.5 mm, 5 mm and 6.3 mm	4.5mm, 5.5 mm and 6mm	3.4 mm, 4.1 mm. 5 and 6 mm	3.5 mm and 6.3 mm	3.4 mm, 4.1 mm and 4.5 mm	Similar, the diameter does not present significant differences.
Connection type	Hex and non-hex	Hex and non-hex	Hex and non-hex	Hex and non-hex	Hex and non-hex	N Hex and non-hex	Same
TEMPORARY ABUTMENT ENGAGING AND NON-ENGAGING							
Material	Titanium grade V	Titanium and peek					Similar
Angulation	Straight	Straight					Yes
Gingival Height	1.11 mm	1.5 and 3 mm					Similar
Post Height	10 mm	10 mm					Same

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	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous UCLA ABUTMENT	Reference Predicate TiUltra Implants and Xeal Abutments	Reference Predicate Temporary Snap Abutment	Reference Predicate TSV BellaTek Express and BellaTek Flex Abutments	Reference Predicate B.T.I. Dental Implant System	Reference Predicate OsseoSpeed TM Profile EV	Equivalence discussion
Diameter	3.7 mm, 4.8 mm and 6 mm	3.5 mm, 5 mm and 6.3 mm					Similar
Connection type	Non Hex	Non Hex					Same as Nobel Active
OSSEOUS UCLA ABUTMENTS							
Material	Titanium grade V			Titanium			Same
Angulation	Straight			Straight			Same
Gingival Height	1.11 mm			0.8 mm			Similar, the gingival height does not present significant differences
Post Height	10 mm			12 mm			Similar, the post height does not present significant differences
Diameter	3.7 mm, 4.8 mm and 6 mm			3.4 mm, 4.1 mm. 5 and 6 mm			Similar
Connection	Non Hex			Non Hex			Same

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	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous UCLA ABUTMENT	Reference Predicate TiUltra Implants and Xeal Abutments	Reference Predicate Temporary Snap Abutment	Reference Predicate TSV BellaTek Express and BellaTek Flex Abutments	Reference Predicate B.T.I. Dental Implant System	Reference Predicate OsseoSpeed TM Profile EV	Equivalence discussion
Type							
INHEX ABUTMENTS							
Material	Titanium grade V					Titanium	Same
Angulation	Straight					Straight	Same
Gingival Height	1.11 mm					1 mm	Similar, the gingival height does not present significant differences
Post Height	10 mm					9 mm	Similar, the post height does not present significant differences
Diameter	3.7 mm, 4.8 mm and 6 mm					3.4 mm, 4.1 mm and 4.5 mm	Similar
Connection Type	Non Hex					Non-Hex	Same
EXTERNAL POST ENGAGING AND NON-ENGAGING							
Material	Titanium grade V				Titanium		Same
Angulation	Straight				Straight		Same
Gingival Height	1.11 mm				1.5 mm and 2 mm		Similar, the gingival height

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	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous UCLA ABUTMENT	Reference Predicate TiUltra Implants and Xeal Abutments	Reference Predicate Temporary Snap Abutment	Reference Predicate TSV BellaTek Express and BellaTek Flex Abutments	Reference Predicate B.T.I. Dental Implant System	Reference Predicate OsseoSpeed TM Profile EV	Equivalence discussion
							does not present significant differences
Post Height	10 mm				9 mm		Similar, the post height does not present significant differences
Diameter	3.7 mm, 4.8 mm and 6 mm				3.4 mm, 4.1 mm and 4.5 mm		Similar
Connection Type	Non Hex				Non-Hex		Same

Table 05.07 Comparison of Principle of Operation and Technological Characteristics – Reference Predicate

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ABUTMENT POST COMPARISON

	TICARE DENTAL IMPLANT SYSTEM Quattro Inhex/Osseous ABUTMENT POSTS	Reference Predicate	Reference Predicate	Equivalence discussion
		B.T.I. Dental Implant System	TiUltra Implants and Xeal Abutments	
Manufacturer	Mozo Grau S.A.	B.T.I. Biotechnology Institute, S.L.	Nobel Biocare AB	-
510 (k) Nº	Pending	K022258	K202344	-
Product Classification	Device Class II Regulation No: 21CFR 872.3640. Product code DZE; Endosseous dental implant	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE, Endosseous Dental Implant abutment	Device Class II Regulation No: 21 CFR 872.3640. Product code DZE, NHA PNP; Endosseous Dental Implant abutment	-
POST FOR TAPERED ABUTMENT				
Material	Titanium grade V	Titanium	Titanium	Same
Angulation	Straight	Straight	Straight	Same
Gingival Height	3.10 mm	1.5 mm and 2 mm	1.5 mm	Similar, the gingival height does not present significant differences.
Post Height	7.9 mm	8 mm	10 mm	Similar, the post height no present significant differences. Post height can be modified to equivalent heights.
Diameter	3.7 mm, 4.8 mm and 6 mm	3.5 mm, 4.1 mm	4.8 mm	Similar
Connection Type	Non Hex	Non Hex	Non Hex	Same

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TEMPORARY COPING MULTIUNIT TITANIUM COMPARISON				
Material	Titanium grade V		Titanium	Same
Angulation	Straight		Straight	Same
Gingival Height	3.10 mm		1.5 mm	Similar, the gingival height does not present significant differences.
Post Height	7.9 mm		10 mm	Similar, the post height does not present significant differences.
Diameter	3.7 mm, 4.8 mm and 6 mm		4.8 mm	Same as 4.8 mm
Connection Type	Non Hex		Non Hex	Same

Table 05.08 Comparison of Principle of Operation and Technological Characteristics – Reference Predicates

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SUBSTANTIAL EQUIVALENCE DISCUSSION:
The subject device is substantially equivalent to BTI Dental Implant System Unic Ca® (K151391) by Biotechnology Institute, S.L
The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function.

In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations.

In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

In terms of equivalence, the indications for use of the subject device are aligned with the indications for use of the primary predicate, including the indications for shorter implants (e.g. 6mm length) and small diameter implants (e.g. 3.3mm).

Regarding the implant design, both subject and predicate devices present internal and external connections with a range of specific diameters and lengths to be combined with abutments within the same system, including angled abutments, to support dental prosthetic restorations.

They both use the same materials, meeting standard specifications.
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SUMMARY DISCUSSION OF NON-CLINICAL DATA:
The subject device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as a dental implant system and following all indications set out in FDA Document “Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments”.

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices:

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- Fatigue testing under the worst-case scenario in accordance with ISO 14801.
- Gamma Sterilization Validation Test under ISO 11137-1 and ISO 11137-2.
- Sterilization validating testing has been performed under ISO 17665-1 for steam sterilization.
- Shelf-life testing according with ASTM F1980, ASTM F88, ASTM F1929 and ISO 11737-2.
- Biocompatibility Tests were performed in accordance with ISO 10993-5 and ISO 10993-23.
- Bacterial Endotoxin Testing (LAL) under USP <85> and USP <161>.
- SEM (Scanning Electron Microscope) and EDS (Energy-dispersive X-ray spectroscopy) were performed to evaluate the final cleaning after surface treatment in Mozo Grau implants.
- Dimensional and mechanical tests on Mozo Grau short implants (< 7 mm length).

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

For devices delivered sterile such as dental implants, a sterility assurance level (SAL) of 10^{-6} have been validated in accordance with ISO 11137-1 “Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices” and ISO 11137-2 “Sterilization of Health Care Products – Radiation – Part 2: Establishing the sterilization dose”. The validation took into account the worst-case scenario, and the results prove equivalence to the predicate device.

For devices delivered non-sterile to be end-user sterilized, the recommended sterilization condition has been validated through the end-user sterilization validation, according to ISO 17665-1 “Sterilization of health care products – Moist heat – part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices”. After a worst-case scenario analysis two steam sterilization validations were conducted, selecting two abutments with the largest masses in two different materials. The results showed equivalence to the predicate device.

Shelf-life Testing was performed on the devices provided sterile in accordance with ASTM F1980 “Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices”. The worst-case scenario was tested, and the results demonstrated that the devices are equivalent to the predicate devices. The shelf-life is guaranteed up to 5 years, and the devices will function adequately as intended without any degradation during the shelf-life.

Packaging tests were carried out according to ASTM F88 to test the seal strength of flexible barrier materials and ASTM F 1929 to detect seal leaks in porous medical packaging by dye penetration. The

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results guarantee shelf life up to 5 years under transport and storage conditions during the shelf-life of <55ºC and humidity <75%.

Sterility tests were performed in accordance with ISO 11737-2 “Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process”, with no microbial growth being detected.

Biocompatibility was assessed under ISO 10993-1. As a result, cytotoxicity and intracutaneous reactivity tests were conducted on several Mozo Grau samples from Mozo Grau Dental Implant System and Abutments in accordance with ISO 10993-5 and ISO 10993-23. The parts selected for testing took into account the worst-case scenario in terms of materials, surfaces, more challenging geometries for cleaning process and direct body tissue contact. The result demonstrated the biocompatibility of the materials used.

Endotoxin (LAL) tests are intended to ensure that devices are not likely to cause pyrogenic reaction. The product selected for testing from Mozo Grau Dental Implant System took into account the worst-case scenario in terms of manufacturing process and was tested for bacterial endotoxin under USP <85> “Bacterial Endotoxins Test”, and USP <161> “Medical Devices – Bacterial Endotoxin and Pyrogen Tests”. The test results have met the acceptance criteria and demonstrated the substantial equivalence with the predicate device.

SEM/EDS chemical characterization was conducted to review the chemical composition of the blasted surface in order to verify that any chemicals used to clean the implant surface after the blasting process have been removed. Characterization of Mozo Grau Sterile Dental Implants concludes that implants are completely clean with no residues from the blasting and cleaning processes on the implant surface, confirming the effectiveness of the cleaning process applied to Mozo Grau dental implants.

A dimensional and mechanical test batch has been performed for the worst-case implant from Mozo Grau Dental Implant System in terms of length. The shortest implant (6 mm long) from Mozo Grau was selected and compared with reference device K172576.
The bone to implant contact surface (BIC) was evaluated under bone level insertion condition and 3mm resorption condition. A favorable result was obtained.
Insertion and removal torque and pull-out strength tests were also performed.
All test results have indicated that the subject device is less critical, having more BIC in all conditions, higher insertion and removal torque and higher pull-out forces, indicating favorable substantial equivalence.

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SUMMARY DISCUSSION OF CLINICAL DATA:
Non-clinical test data are submitted to support this premarket notification and to establish substantial equivalence. No clinical studies are submitted.

MR Environment Condition
Non-clinical worst-case MRI review was performed to evaluate the metallic Ticare devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

SUMMARY OF SUBSTANTIAL EQUIVALENCE DISCUSSION:
When compared to the primary and reference predicate devices, the intended use and technological characteristics of Ticare Dental Implant Systems raise no new issues related to safety and effectiveness. Ticare Dental Implant Systems are found to be substantially equivalent to the primary predicate device BTI Dental Implant System UnicCa® (K151391).

CONCLUSIONS:
Based on the results of the bench testing performed and information included in this submission, we conclude that the Ticare Dental Implant Systems are substantially equivalent to the primary predicate device.