March 4, 2025

Euroteknika
% Justin Gracyalny
Regulatory Affairs Manager
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K232383
Trade/Device Name: iPhysio® System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 7, 2025
Received: February 7, 2025

Dear Justin Gracyalny:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232383

Device Name
iPhysio® System

Indications for Use *(Describe)*

Indications for Use for iPhysio® Profile Designer:
iPhysio® System Profile Designers are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. The healing abutments should be used only with compatible implant connections. The healing abutments are intended for use up to 6 months.

Compatible Implant Systems:

Manufacturer	Implant System	Implant Diameter (mm)	Platform Diameter (mm)	Platform Name
Nobel Biocare	NobelActive®	3.5	3.5	NP
Nobel Biocare	NobelActive®	4.3, 5.0	4.3, 5.0	RP
Nobel Biocare	NobelReplace®	3.5	3.5	NP
Nobel Biocare	NobelReplace®	4.3, 5.0	4.3, 5.0	RP
Nobel Biocare	NobelParallel™	3.75	3.5	NP
Nobel Biocare	NobelParallel™	4.3, 5.0	4.3, 5.0	RP
Straumann	Bone Level	3.3	3.3	NC
Straumann	Bone Level	4.1, 4.8	4.1, 4.8	RC
Straumann	Bone Level Tapered	3.3	3.3	NC
Straumann	Bone Level Tapered	4.1, 4.8	4.1, 4.8	RC
Zimmer Biomet	Trabecular Metal	3.7, 4.1	3.5	3.5
Zimmer Biomet	Trabecular Metal	4.7	4.5	4.5
Zimmer Biomet	Tapered Screw Vent	3.7, 4.1	3.5	3.5
Zimmer Biomet	Tapered Screw Vent	4.7	4.5	4.5

Indications for Use for iPhysio® PEEK Temporary Abutment:
The iPhysio® System PEEK Temporary Abutment is an abutment placed on the iPhysio® System Profile Designer to provide support for prosthetic structures for up to 6 months. It can be used in single- or two-stage procedures and is intended to be placed out of occlusion.

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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K232383
510(k) SUMMARY:
iPhysio® System

Date Prepared	March 4, 2025
Sponsor	Euroteknika 726 Rue Du General De Gaulle Sallanches Haute-Savoie, France 74700 +33 6 83 01 50 23
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE Linda Braddon, Ph.D. 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	iPhysio® System
Common Name	Abutment, Implant, Dental Endosseous
Code – Classification	NHA 21 CFR §872.3630: Class II
Predicate Device	K192893 Straumann® Ceramic Healing Abutments
Reference Devices	K220022 Sigma Biomedical TRATE Dental Implant System K173374 Biomet 3i, Inc. TSV™ BellaTek® Encode® Healing Abutments K212628 Terrats Medical SL DESS Dental Smart Solutions K231803 JJGC Industria e Comercio de Materiais Dentarios SA Neodent Implant System - Zirconia Implant System K220200 Paltop Advanced Dental Solutions, Ltd Paltop Conical Implant System
Reference Devices for Compatible OEM Implant System	K071370 Nobel Biocare AB NobelActive Internal Connection Implant K073142 Nobel Biocare LLC USA NobelReplace Hexagonal Implant K173418 Nobel Biocare AB NobelParallel™ Conical Connection K121131 Straumann USA BL, 04.1 MM RC, SLACTIVE 8MM, TIZR AND 10MM, 12, 14MM K140878 Straumann USA Bone Level Tapered Implant K083550 Straumann USA Dental Implant System K133339 Zimmer Dental Tapered Screw Vent T Implant, HA Coated; Tapered Screw-Vent M Implant, HA Coated
Device Description	The iPhysio® System is a set of two-piece titanium healing abutments (iPhysio® Profile Designers) be screwed into the implant using compatible anodized titanium screws during the 1st or the 2nd surgical intervention. The iPhysio® Profile Designer abutment is manufactured from titanium alloy (Ti-6Al-4V ELI) per ISO 5832-3 and includes a zirconium nitride (ZrN) coating. iPhysio® Profile Designers are available in multiples anatomical shapes and gingival heights, and are compatible with Nobel BioCare (NobelActive®, NobelReplace®, NobelParallel™), Straumann (Bone Level / Bone Level Tapered), and Zimmer Biomet (Trabecular Metal, Tapered Screw-Vent®) implants. All iPhysio® Profile

	Designers are straight (0°). Supporting screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ISO 5832-3 and are anodized to a color that aligns with its corresponding height. The iPhysio® Profile Designer healing abutment screw is for placing the iPhysio® Profile Designer in the implant in the patient's mouth. The iPhysio® Profile Designer remains in place throughout the bone and gingival healing process as well as during the taking of a digital or conventional impression, preserving the emergence profile during the impression. The abutment is only removed once to place and finally screw in the final abutment. Anatomical healing, implant impression, and placement of the temporary crown may all be done without removing the iPhysio® Profile Designer. A compatible PEEK temporary abutment may be clipped to the iPhysio® Profile Designer to which a non-load bearing temporary crown may be then placed for improved aesthetics during healing. To use the PEEK temporary abutment, the iPhysio® Profile Designer healing abutment screw is replaced with a compatible temporary abutment screw. The temporary crown is placed over the PEEK temporary abutment following modification of the abutment to the appropriate shape. The PEEK temporary abutment is connected onto the iPhysio® Profile Designer by a combination of friction and cement. All iPhysio® temporary abutments are manufactured from PEEK per ASTM F2026.
Indications for Use Statement	Indications for Use for iPhysio® Profile Designer: iPhysio® System Profile Designers are indicated to be placed in the patient's mouth at the end of the implant placement to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. The healing abutments should be used only with compatible implant connections. The healing abutments are intended for use up to 6 months. Compatible Implant Systems:

Manufacturer	Implant System	Implant Diameter (mm)	Platform Diameter (mm)	Platform Name
Nobel Biocare	NobelActive®	3.5	3.5	NP
		4.3, 5.0	4.3, 5.0	RP
	NobelReplace®	3.5	3.5	NP
		4.3, 5.0	4.3, 5.0	RP
	NobelParallel™	3.75	3.5	NP
		4.3, 5.0	4.3, 5.0	RP
Straumann	Bone Level	3.3	3.3	NC
		4.1, 4.8	4.1, 4.8	RC
	Bone Level Tapered	3.3	3.3	NC
		4.1, 4.8	4.1, 4.8	RC
Zimmer Biomet	Trabecular Metal	3.7, 4.1	3.5	3.5
		4.7	4.5	4.5
	Tapered Screw-Vent®	3.7, 4.1	3.5	3.5
		4.7	4.5	4.5

	Indications for Use for iPhysio® PEEK Temporary Abutment: The iPhysio® System PEEK Temporary Abutment is an abutment placed on the iPhysio® System Profile Designer to provide support for prosthetic structures for up to 6 months. It can be used in single- or two-stage procedures and is intended to be placed out of occlusion.

Comparison of Technological Characteristics – Healing Abutment

<table>
<tr><th>Characteristic</th><th>Subject Device
Euroteknika
iPhysio® System</th><th>Primary Predicate
Straumann
Ceramic Healing Abutments
K192893</th><th>Reference Device
Sigma Biomedical
TRATE Dental Implant System
K220022</th><th>Reference Device
Biomet 3i
TSV™ BellaTek® Encode® Healing Abutments
K173374</th><th>Reference Device
Terrats Medical SL
DESS Dental Smart Solutions
K212628</th></tr>
<tr><td>Purpose</td><td>Subject Device</td><td>Same indications; Similar components (screw retained healing abutment)</td><td>Similar healing abutment sizes</td><td>Similar impression taking process</td><td>Similar materials of construction and healing abutment coating</td></tr>
<tr><td>Product Classification</td><td>Class II
872.3630
Primary: NHA</td><td>Class II
872.3630
Primary: NHA</td><td>Class II
872.3630
Primary: DZE, NHA</td><td>Class II
872.3630
Primary: NHA</td><td>Class II
872.3630
Primary: NHA</td></tr>
<tr><td>Indications for Use</td><td>Indications for Use for iPhysio® Profile Designer: iPhysio® System Profile Designers are indicated to be placed in the patient’s mouth at the end of the implant placement to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. The healing abutments should be used only with compatible implant connections. The healing abutments are intended for use up to 6 months.

Compatible Implant Systems:
<table>
<tr><th>Manufacturer</th><th>Implant System</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th><th>Platform Name</th></tr>
<tr><td rowspan="8">Nobel Biocare</td><td rowspan="2">NobelActive®</td><td>3.5</td><td>3.5</td><td>NP</td></tr>
<tr><td>4.3, 5.0</td><td>4.3, 5.0</td><td>RP</td></tr>
<tr><td rowspan="2">NobelReplace®</td><td>3.5</td><td>3.5</td><td>NP</td></tr>
<tr><td>4.3, 5.0</td><td>4.3, 5.0</td><td>RP</td></tr>
<tr><td rowspan="2">NobelParallel™</td><td>3.75</td><td>3.5</td><td>NP</td></tr>
<tr><td>4.3, 5.0</td><td>4.3, 5.0</td><td>RP</td></tr>
<tr><td rowspan="2">Straumann</td><td rowspan="2">Bone Level</td><td>3.3</td><td>3.3</td><td>NC</td></tr>
<tr><td>4.1, 4.8</td><td>4.1, 4.8</td><td>RC</td></tr>
<tr><td rowspan="2">Straumann</td><td rowspan="2">Bone Level Tapered</td><td>3.3</td><td>3.3</td><td>NC</td></tr>
<tr><td>4.1, 4.8</td><td>4.1, 4.8</td><td>RC</td></tr>
<tr><td rowspan="4">Zimmer Biomet</td><td rowspan="2">Trabecular Metal</td><td>3.7, 4.1</td><td>3.5</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td><td>4.5</td></tr>
<tr><td rowspan="2">Tapered Screw-Vent®</td><td>3.7, 4.1</td><td>3.5</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td><td>4.5</td></tr>
</table></td><td>Straumann® Ceramic Healing abutments are indicated to be placed in the patient’s mouth at the end of the implant placement to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Healing abutments should be used only with suitable implant connections. The healing components are intended to be used up to 6 months</td><td>TRATE Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. TRATE Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading</td><td>The TSV™ BellaTek® Encode® Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for a acceptance of a final abutment and restoration.</td><td>DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture</td></tr>
<tr><td>Device Classification Name</td><td>Endosseous Dental Implant Abutment</td><td>Endosseous Dental Implant Abutment</td><td>Endosseous Dental Implant Abutment</td><td>Endosseous Dental Implant Abutment</td><td>Endosseous Dental Implant Abutment</td></tr>
<tr><td>Intended Use</td><td>Protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.</td><td>Protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.</td><td>Protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.</td><td>Protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.</td><td>Protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.</td></tr>
<tr><td>Sterilization</td><td>Sterile, Gamma Irradiation
SAL 10-6</td><td>Sterile, Ethylene Oxide
SAL 10-6</td><td>Sterile, End User Steam Sterilized
SAL 10-6</td><td>Sterile, Gamma Irradiation
SAL 10-6</td><td>Non-Sterile, End User Steam Sterilized
SAL 10-6</td></tr>
</table>

Characteristic	Subject Device Euroteknika iPhysio® System	Primary Predicate Straumann Ceramic Healing Abutments K192893	Reference Device Sigma Biomedical TRATE Dental Implant System K220022	Reference Device Biomet 3i TSV™ BellaTek® Encode® Healing Abutments K173374	Reference Device Terrats Medical SL DESS Dental Smart Solutions K212628
Abutment / Screw Material	Abutment: ZrN coated Titanium alloy Screw: Titanium alloy	Abutment: Y-TZP Screw: Ti-6Al-7Nb or TAN (screw)	Abutment: Titanium alloy Screw: Titanium alloy	Abutment: Titanium alloy Screw: Titanium alloy	Abutment: ZrN coated and uncoated Titanium alloy (Ti-6Al-4V ELI) Screw: Titanium alloy (Ti-6Al-4V) with and without a diamond like coating
Abutment Shape	4 abutment forms • A: Incisors, Canines, and Premolars • B: Premolar, Molar, and Maxillary Central Incisors • C: Molar • D: Premolars	Circular Design	Circular Design	Circular Design with Various Emergence Profiles 3.8, 5.0, 5.6, 6.0, and 6.8mm	Not applicable to comparison
Implant Abutment Connection	Internal	Internal	Internal	Internal	Not applicable to comparison
Abutment Sizes	Total Height: 7.2 – 10.6 mm Abutment Length: 4.3 – 7.7 mm Abutment Width: 4.3 – 6.6 mm	Total Height: NC: 8 to 11 mm RC: 8 to 12 mm Abutment Diameter: NC: Ø3.6 & 4.8 mm RC: Ø4.5, 5.0, 6.0, and 6.5 mm	Abutment Diameter: 4mm, 5mm	Platform Diameter: 3.5, 4.5, 5.7mm	Not applicable to comparison
Abutment Angle	Straight (0°)	Straight (0°)	Straight (0°)	Straight (0°)	Not applicable to comparison
Abutment Gingival Heights (mm)	1mm, 2mm, 3mm, and 4mm	2.0, 3.0, and 4.5 mm	0.5mm – 7mm	3, 5, and 7mm	
Abutment Method of Attachment	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw
Impression Compatibility	Does not require removal of iPhysio® Profile Designer abutment when taking digital / conventional impressions	Requires removal of healing abutment when taking impressions	Requires removal of healing abutment when taking impressions	Does not require removal of healing abutment when taking digital / conventional impressions	Not applicable to comparison
Abutment Loading	Not intended to be load bearing	Not intended to be load bearing	Not intended to be load bearing	Not intended to be load bearing	Not applicable to comparison

Characteristic	Subject Device Euroteknika iPhysio® System	Primary Predicate Straumann Ceramic Healing Abutments K192893	Reference Device Sigma Biomedical TRATE Dental Implant System K220022	Reference Device Biomet 3i TSV™ BellaTek® Encode® Healing Abutments K173374	Reference Device Terrats Medical SL DESS Dental Smart Solutions K212628
Compatible Implants	Nobel Biocare NobelActive®: Narrow Platform (NP) and Regular Plarform (RP) Nobel Biocare NobelReplace® CC: Narrow Platform (NP) and Regular Plarform (RP) Nobel Biocare NobelParallel™ CC: Narrow Platform (NP) and Regular Plarform (RP) Straumann Bone Level (BL) and Bone Level Tapered (BLT) Ø3.3: Narrow CrossFit® Connection (NC) Straumann Bone Level (BL) and Bone Level Tapered (BLT) Ø4.1 and Ø4.8: Regular CrossFit® Connection (RC) Zimmer Biomet Screw Vent / Tapered Screw-Vent®, Trabecular Metal™: platform Ø 3.5 green and Ø 4.5 purple	Straumann Dental Implant Systems: Narrow CrossFit® (NC) and Regular CrossFit® (RC)	TRATE Dental Implant System Implants: Narrow and Regular Standard	Tapered Screw-Vent®, Screw-Vent® and Trabecular Metal implant systems	Not applicable to comparison

Comparison of Technological Characteristics – PEEK Temporary Abutment

Characteristic	Subject Device Euroteknika iPhysio® System	Additional Predicate JJGC Industria e Comercio de Materiais Dentarios SA Neodent Implant System - Zirconia Implant System K231803	Additional Predicate Paltop Advanced Dental Solutions, Ltd Paltop Conical Implant System K220200
Purpose	Subject Device	Similar cylindrical pillar design (temporary abutment)	Similar intended use and technological characteristics (SAS Abutment)
Product Classification	Class II 872.3630 Primary: NHA	Class II 872.3630 Primary: NHA	Class II 872.3630 Primary: DZE, NHA
Device Classification Name	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment
Indications for Use	Indications for Use for iPhysio® PEEK Temporary Abutment: The iPhysio® System PEEK Temporary Abutment is an abutment placed on the iPhysio® System Profile Designer to provide support for prosthetic structures for up to 6 months. It can be used in single- or two-stage procedures and is intended to be placed out of occlusion.	Indications for Use for PEEK CR Abutment for Zirconia Implant System: The PEEK CR Abutment is indicated to be used on Neodent Implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.	The Paltop Conical Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Narrow diameter implants are intended for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots. The Paltop Conical Implant System is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Intended Use	Support of a temporary provisional prosthesis placed out of occlusion	Support of a temporary provisional prosthesis placed out of occlusion	Support of a temporary provisional prosthesis placed out of occlusion
Sterilization	Non-Sterile, End User Steam Sterilized SAL 10-6	Sterile, Ethylene Oxide SAL 10-6	Non-Sterile, End User Steam Sterilized SAL 10-6
Abutment Design	Cylindrical pillar that snaps to healing abutment	Two-piece cylindrical abutment with through hole to fixate the screw and abutment base	Cap that snaps to screw-retained titanium abutment
Implant-Abutment Interface	Snaps to healing abutment and supported by cement	Straight internal connection indexing features (ZiLock)	Snaps to healing abutment and supported by cement
Temporary Abutment Material	PEEK	PEEK	PEEK
Abutment Gingival Heights	Component snaps on top of healing abutment. Gingival height determined via healing abutment (1-4mm)	1.5mm, 2.5mm, 3.5mm, 4.5mm	Component snaps on top of healing abutment. Gingival height is determined via healing abutment (1-5mm).
Abutment Diameters	3.0mm	4.0mm, 4.5mm	4.5mm
Modifiable by End User to Final Geometry	Yes	Yes	Yes

Equivalence to Marketed Devices

There are no significant technological differences between the subject and predicate devices. The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Additional reference devices not discussed below are identified only for OEM implant system compatibility.

Healing Abutments

The subject device healing abutments are substantially equivalent in intended use to the primary predicate device cleared in K192853 and the additional predicate devices cleared in K220022, K173374, and K212628. All subject device abutments are substantially equivalent in design, materials, and technological characteristics to the additional predicate devices. Minor differences include:

- The inclusion of a ZrN coating is similar to K212628 and supporting coating characterization testing supports that the coating fulfills all necessary requirements for its intended use. As such, this difference does not raise new concerns for safety or effectiveness.
- The subject device healing abutment is offered of various geometrical forms depending on the location of the abutment in the mouth. The predicate devices are only offered in a circular form. As shown via the engineering analyses, these differences in forms do not impact device compatibility. As such, this difference does not raise new concerns for safety or effectiveness.
- The subject and predicate device healing abutments are compatible with different implants. Reverse engineering analyses support that the subject device was shown to be compatible with all devices as listed in the labeling and indications for use. As such, this difference does not raise new concerns for safety or effectiveness.
- The Indications for Use Statement (IFU) for the subject device is substantially equivalent to that of the primary predicate K192853. Any differences in the indications are simply to indicate the list of compatible implants.

In conclusion, any technological differences between the subject and predicate devices do not raise new concerns for safety or effectiveness.

PEEK Temporary Abutments

The subject device PEEK temporary abutments are substantially equivalent in intended use to the additional predicate devices cleared in K231803 and K220200. All subject device PEEK temporary abutments are substantially equivalent in design, materials, and technological characteristics to the additional predicate devices. Minor differences include:

- The subject device PEEK temporary abutment has a different mechanism of connection from the additional predicate devices. Bench testing including dynamic fatigue testing and abutment removal testing supports that the subject device temporary abutment can withstand worst case loading for the maximum indicated duration of use and the temporary abutment connection

feature does not cause damage to either the implant or healing abutment. As such, this difference does not raise new questions of safety or effectiveness.

- The subject device PEEK temporary abutment is indicated for a maximum duration of 180 days while K220200 is indicated for use for only 30 days. This difference is addressed via K231803 which is also indicated for a maximum use of 180 days. As such, this difference does not raise new questions of safety or effectiveness.
- The subject device PEEK temporary abutment is a pillar that can be modified to shape prior to placement of the temporary prosthesis. K220200 is a cap that cannot be modified after placement. This technological difference is addressed via K231803 which also includes a PEEK pillar shaped abutment that can be modified to shape prior to placement of the temporary prosthesis. As such, this difference does not raise new questions of safety or effectiveness.

In conclusion, any technological differences between the subject and predicate devices do not raise new concerns for safety or effectiveness.

Non-Clinical Performance Testing Summary

Performance testing for the subject device is summarized in the table below:

Test	Test Method Summary	Results
Reverse Engineering Analysis	Reverse engineering analysis of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility. Relevant dimensions and tolerances from subject device screw and abutment connections were analyzed for compatibility with FDA cleared implants as specified in the device labeling.	**PASS** Device met all predetermined acceptance criteria
ZrN Coating Characterization	Per FDA Guidance "Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Class II Special Controls Guidance Document for Industry and FDA Staff" • ZrN Coating Cross Section SEM Imaging Test Report • ZrN Coating Elemental Analysis and SEM Imaging Test Report • ZrN Coating Hardness Abrasion Scratch Test • ZrN Coating Tensile Shear and Abrasion Test	**PASS** Coating met all predetermined acceptance criteria
MR Compatibility Testing	Per ASTM F2503-20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment and FDA Guidance Document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment"	**PASS** Device is MR Conditional

Test	Test Method Summary	Results
Fatigue Testing	All subject device abutments are straight (0°), are intended to be placed in occlusion, and are not intended to correct angled implants. As such, there would be no forces applied to them and thus, dynamic fatigue testing is not applicable.	
	Fatigue testing was conducted to evaluate the temporary abutments in a worst-case test configuration. The test setup was based on a modified version of ISO 14801:2016	**PASS** Device met all predetermined acceptance criteria

The subject device components were evaluated for biocompatibility according to ISO 10993-1 and the FDA Guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The following testing was performed to support the biocompatibility of the subject device:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-23
- Acute Systemic Toxicity per ISO 10993-11
- Material Mediate Pyrogenicity per ISO 10993-11, European Pharmacopoeia – 2.6.8. Pyrogens
- Implantation per ISO 10993-6
- Subacute / subchronic toxicity, chronic toxicity, genotoxicity, and carcinogenicity were addressed via chemical characterization per ISO 10993-18 and toxicological risk assessment per ISO 10993-17

The iPhysio® Profile Designer and all supporting components were found to be biocompatible for their intended contact level and duration when tested in compliance with ISO 10993-1.

A gamma sterilization validation in compliance with ISO 11137-2 was performed confirming the applicable cycle will achieve a sterility assurance level (SAL) of 10^{-6} for the worst-case packaging configuration. A steam sterilization in compliance with ISO 17665-1 was performed confirming the applicable cycle will achieve a sterility assurance level (SAL) of 10^{-6} for the subject device non-sterile components. Sterile packed components were tested in accordance with ISO 11607-1 to validate the labeled shelf life.

Clinical Performance Testing Summary

No clinical data was included in this submission.

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.