JJGC Indústria e Comércio de Materiais Dentários S.A.
℅ Jennifer Jackson
Sr. Director, Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

May 2, 2024

Re: K233857
Trade/Device Name: Neodent Implant System - Custom Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 2, 2024
Received: April 2, 2024

Dear Jennifer Jackson:

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)*
K233857

Device Name
Neodent Implant System – Custom Abutments

Indications for Use *(Describe)*

Custom Abutment Ti with Screw (milled):
The Custom Abutment Ti with Screw is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Custom Abutments Ti with Screw are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom Abutment Ti with Screw are intended to be sent to Straumann for manufacturing at a validated milling center.

Custom Abutment Ti with Angled Screw Channel (milled):
The Custom Abutment with Angled Screw Channel is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Custom Abutments with Angled Screw Channel are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom Abutment Ti with Angled Screw Channel are intended to be sent to Straumann for manufacturing at a validated milling center.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K233857 Traditional 510(k) Submission

Neodent Implant System – Custom Abutments

510(k) Summary

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: JJGC Indústria e Comércio de Materiais Dentários AS (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Paraná, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023
Prepared By & Alternate Contact:	Leticia Milani Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: leticia.milani@neodent.com
Date Prepared:	May 2, 2024

Name of the Device

Trade Names:	Neodent Implant System – Custom Abutments
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630, Class II
Device Classification:	II
Product Code(s):	NHA
Classification Panel:	Dental Products Panel

K233857 Traditional 510(k) Submission

Neodent Implant System – Custom Abutments

510(k) Summary

Predicate Device(s)

Primary Predicate:

- *K203309 – Nuvo CF Implant System (JJGC Indústria e Comércio de Materiais Dentários S.A)*

Reference Devices:

- *K150367 – Neodent Implant System – CM Preface Abutment (JJGC Indústria e Comércio de Materiais Dentários S.A)*
- *K162890 – Straumann SC CARES Abutment (Straumann USA, LLC)*
- *K182620 – MRI Compatibility For Existing Neodent Implant System*

Device Description

The Custom Abutments subject to this submission are similar to the devices already cleared in previous Neodent and Nuvo Implant System submissions, per the predicate and reference devices described above. This submission intends to expand the portfolio of digital abutments for the Grand Morse (GM), Narrow Grand Morse (NGM) and Helix Short (HS) lines, to provide more treatment options for customers. These abutments are composed of a unique body with two regions: the upper region is the customized portion, while the end region presents the prosthetic interface that fits with the implant, which does not allow customization.

They are intended for single use and provided non-sterile, with their sterilization recommended before installation in the mouth.

All proposed abutments are delivered to the final user already customized in a validated milling center, with a straight channel solution. For the GM line, the abutments could also be milled with a new angled channel solution for the screw access. All subject devices must be used with their corresponding prosthetic interface.

Intended Use

The Custom Abutments are used onto dental implants to provide support for customized prosthetic restorations (copings and crowns), indicated for screw-retained or cement-retained single restorations. They are indicated according to the interocclusal space available, existing transmucosal height and three-dimensional position of the implant. The subject devices are available in GM, NGM and HS prosthetics interfaces compatible with the implants of the prosthetic interface.

Indications for Use

The Custom Abutment Ti with Screw is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Custom Abutments Ti with Screw are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom Abutment Ti with Screw are intended to be sent to Straumann for manufacturing at a validated milling center.

The Custom Abutment with Angled Screw Channel is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specifics CAD/CAM software according to digital dentistry workflow. Custom Abutments with Angled Screw Channel are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom Abutment Ti with Angled Screw Channel are intended to be sent to Straumann for manufacturing at a validated milling center.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following tables:

Table 11 – Comparison of subject device and predicate device Custom Abutments

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
K Number	Neodent Implant System Customizable Abutments	K203309 Nuvo CF Implant System	K162890 Straumann SC CARES Abutment	K150367 Neodent Implant System – CM Preface Abutment
Indications for Use	The Custom Abutment Ti with Screw is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specific CAD/CAM software according to digital dentistry workflow. Custom Abutments Ti with Screw are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom Abutment Ti with Screw are intended to be sent to Straumann for manufacturing at a validated milling center. The Custom Abutment with Angled Screw Channel is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations. All abutments are only intended to be digitally designed and manufactured using specific CAD/CAM software according to digital dentistry workflow. Custom Abutments with Angled Screw Channel are indicated for screw-retained single restorations or cemented-retained single or multiple restorations. All digitally designed abutments for use with the Custom Abutment Ti with Angled Screw Channel are intended to be sent to Straumann for manufacturing at a validated milling center.	The CARES® Abutment CF is a customized prosthetic abutment, manufactured in titanium alloy, placed onto dental implants to provide support for customized prosthetic restorations (copings or crowns). It is indicated for screw-retained or cement-retained single-unit restorations. All digitally designed abutments for use with the CARES® Abutment are intended to be sent to Straumann for manufacturing at a validated milling center.	Straumann SC CARES® abutments are indicated for single-tooth replacements and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.	PreFace Abutment is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. PreFace Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations.
Material	Devices: Titanium alloy, according to ASTM F136. Screw: Titanium alloy, according to ASTM F136 or TAN.	Devices: Titanium alloy, according to ASTM F136. Screw: Titanium alloy, according to ASTM F136.	Devices: TAN Screw: TAN	Devices: Titanium alloy, according to ASTM F136. Screw: Titanium alloy, according to ASTM F136.
Implant-Abutment Connection	Grand Morse and Narrow Grand Morse HS: Internal Hex	Internal Hex	SC Internal Connection	Cone Morse
Channel Solution	Straight and angled	Straight	Straight	Straight

Traditional 510(k) Submission

Neodent Implant System – Custom Abutments

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
K Number	Neodent Implant System Customizable Abutments	K203309 Nuvo CF Implant System	K162890 Straumann SC CARES Abutment	K150367 Neodent Implant System – CM Preface Abutment
Minimum Wall Thickness	0.4mm	0.4mm	0.4mm	0.4mm
Gingival Height	NGM Customized abutment 0.6-5.8mm HS Customized abutment 0.2-5.4mm** GM Customized abutment 0.6-5.8mm GM Customized abutment with angled screw channel 0.6-5.6mm	Minimum 0.8mm	Minimum 0.1mm	Min 0.6mm
Maximum Gingival Height	NGM Customized abutment 5.8mm HS Customized abutment 5.4mm GM Customized abutment with angled screw channel 5.6mm GM Customized abutment 5.8mm	5.8mm		3.5mm
Abutment Post Height*	Minimum 4.0mm	Minimum 4.0mm	Minimum 6mm	Minimum 4.0mm
Maximum Abutment Angulation Customization	30º	30°	30°	30°
Single Use	Yes	Yes	Yes	Yes
Sterilization Method	Provided non-sterile. Terminally sterilized by user via moist heat. Moist heat cycle parameters have been validated to a SAL of $1x10^{-6}$.	Provided non-sterile. Terminally sterilized by user via moist heat. Moist heat cycle parameters have been validated to a SAL of $1x10^{-6}$.	Provided non-sterile. Terminally sterilized by user via moist heat. Moist heat cycle parameters have been validated to a SAL of $1x10^{-6}$.	Provided non-sterile. Terminally sterilized by user via moist heat. Moist heat cycle parameters have been validated to a SAL of $1x10^{-6}$.

*Post height is the length above the abutment collar/gingival height.

**Helix Short (HS) Implant System, K223638, is a tissue level implant system.

Performance Testing

Bench Testing

Assessment regarding dynamic fatigue testing was conducted according to the FDA guidance document "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" and ISO 14801 "*Dentistry — Implants — Dynamic loading test for endosseous dental implants*". For dynamic fatigue tests, the results demonstrated that in identical conditions the subject devices exhibit a level of performance equivalent to that reviewed for the presented predicate devices.

Torsion tests were performed to evaluate the strength of the screw used to fix all subject abutments against maximum twisting forces. The results prove that there is an adequate torsion strength of 2.0 N-cm over the indicated installation torque.

Sterilization Validation

Sterilization validation was performed 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" and ISO 17665-2 "Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1, as provided in K180536. A minimum Sterility Assurance Level (SAL) of $1x10^6$ has been validated for this method. The subject devices are not represented to be "non-pyrogenic".

MR Compatibility Testing

The MR compatibility was performed to assess the risk of exposing patients who have implantable medical devices. An assessment was made to demonstrate that the subject devices do not configure a new worst case and can be represented by the previously conducted studies reviewed for reference devices, since both have the same raw material and similar dimensions. The subject devices are therefore MR conditional devices and a patient treated with the subject devices can be safely scanned observing the parameters previously established per reference devices.

Biocompatibility Testing

A biological assessment was performed according to ISO 10993-1 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" and to 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', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016*". Representative samples of the subject devices were subjected to the following:

• Biocompatibility sample preparation was made according to ISO 10993-12.

• Biological Safety Assessment guided by ISO 10993-1.

• Chemical characterization was performed per ISO 10993-18.

• Cytotoxicity testing was performed per ISO 10993-5.

The subject devices are equivalent in material and manufacturing processes to the primary predicate and reference devices, therefore, no new issues regarding biocompatibility were raised and no additional biocompatibility testing was required.

Conclusion

The documentation submitted in this premarket notification demonstrates the subject devices are substantially equivalent to the primary predicate and reference devices.