May 27, 2025

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

Re: K250614
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: February 28, 2025
Received: February 28, 2025

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.

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250614

Please provide the device trade name(s).

Neodent Implant System - Custom Abutments

Please provide your Indications for Use below.

Custom Abutment AS Ti:
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.

ASC Screw:
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Please select the types of uses (select one or both, as applicable).

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

Traditional 510(k) Submission

Neodent Implant System

K250614

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810, USA Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: JJGC Indústria e Comércio de Materiais Dentários S.A (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 Email: jennifer.jackson@straumann.com
Prepared By & Alternate Contact:	Leticia Milani Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA
Date Prepared:	May 21, 2025

Name of the Device

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

Traditional 510(k) Submission

Neodent Implant System

K250614

Predicate Device(s)

Primary Predicate:

- *K233857 – Neodent Implant System – Custom Abutments*

Reference Devices:

- *K163194 – Neodent Implant System – GM Line*
- *K182620 – MRI Compatibility for Existing Neodent Implant System*

Device Description

This premarket notification includes new digital abutments to the Neodent Implant System (GM, NGM and HS prosthetic interfaces). The abutments proposed on this submission are identical to devices already cleared in previous submissions of Neodent Implant System, according to predicate devices described above, being the only difference between them the introduction of a new angled channel solution. This submission intends to expand the portfolio of Neodent Implant System. The Custom Abutments AS Ti are composed of a unique body with two different regions: the upper region, which is the customizable portion, and the end region presents the prosthetic interface that fits with the implant, which does not allow customization. They must be sent to a Straumann Validated Milling

Intended Use

The Custom Abutments AS Ti are used onto dental implants to provide support for customized prosthetic restorations (copings and crowns). They are indicated according to the interocclusal space available, existing transmucosal height and three-dimensional position of the implant. The ASC Screws are intended to attach the intermediate to the implant.

Indications for Use

Custom Abutment AS Ti:

The Customized 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.

ASC Screw:

The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Technological Characteristics

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

Table 1 – Table of Substantial Equivalence for proposed devices.

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
K Number	-	***K233857*** ***Neodent Implant System – Custom Abutments***	***K163194*** ***Neodent Implant System – GM Line***
Indications for Use	Custom Abutment AS: 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. ASC Screw: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Custom Abutment AS: 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.	Screw: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Material	Device and Screw: Titanium alloy, according to ASTM F136.	Device and Screw: Titanium alloy, according to ASTM F136.	Screw: Titanium alloy, according to ASTM F136.
Implant Abutment Connection	Narrow Grand Morse (NGM) Helix Short (HS)	Grand Morse (GM) Narrow Grand Morse (NGM) Helix Short (HS)	Grand Morse (GM)
Channel Solution	Angled	Straight and angled	
Maximum Customization Angulation	30°	30°	

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
K Number	-	***K233857*** ***Neodent Implant System – Custom Abutments***	***K163194*** ***Neodent Implant System – GM Line***
Maximum Channel Angulation	25°	25°	
Minimum Wall Thickness	0.4 mm	0.4 mm	
Minimum Abutment Post Height	4 mm	4 mm	
Gingival Height	Angled screw channel NGM: 0.6 - 8.6mm HS: tissue level implant system, GH is given by the implant design **	Straight screw channel GM: 0.6 – 5.8 mm NGM: 0.6 – 5.8 mm HS: 0.2 – 5.4 mm** Angled screw channel GM: 0.6 – 5.6mm Note: The maximum gingiva height reported above represents the maximum gingiva height tested in the ISO 14871 dynamic fatigue set up. The maximum gingiva height that the blank allows milling to considering the 4mm minimum abutment post height is the following: Straight screw channel: GM interface: 0.6 - 8.6 mm NGM interface: 0.6 - 8.6 mm HS interface: tissue level implant system, GH is given by the implant design ** Angled screw channel GM: 0.6 – 8.6 mm	
Fabrication Workflow	Milling by Straumann centralized validated milling center	Milling by Straumann centralized validated milling center	
Single use	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 $1x10^{-6}$.	

*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

Assessments regarding dynamic fatigue testing were 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, a worst case analysis determined that the subject devices are not a new worst case compared to those devices tested for the primary predicate. Therefore, no new testing was provided in this submission. Torsion tests were also 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 in accordance with the installation torque recommended in IFU.

Biocompatibility Testing

Assessments regarding biological compatibility were 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:

- 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.

Sterilization validation

The proposed devices are delivered non-sterile and must be sterilized before installation in the mouth, the steam sterilization method was validated 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*", using the parameters described in IFU. The sterilization of the subject device are identical to the sterilization already cleared for the primary and reference predicate devices.

MRI Compatibility Testing

An assessment was made to demonstrate that the MR conditional labeling from K182620 is applicable to the subject devices, and a patient treated with them can be safely scanned observing the parameters previously established per reference devices.

Conclusion

The subject, primary predicate and reference devices have similar indications for use, intended use, design, raw material and overall dimensions. Thus, all documentation submitted in this premarket notification demonstrate that they are substantially equivalent.