July 02, 2026

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

Re: K261147
Trade/Device Name: Neodent Implant System - NeoConvert Fit
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 7, 2026
Received: April 7, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Sherrill Lathrop Blitzer

for Andrew 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.	K261147

Please provide the device trade name(s).

Neodent Implant System - NeoConvert Fit

Please provide your Indications for Use below.

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. The NeoConvert Fit Solution may be used with single-stage or two-stage procedures, for temporary 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).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Traditional 510(k) Submission

Neodent Implant System - NeoConvert Fit

K261147 - 510(k) Summary

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
Prepared By & Alternate Contact:	Leticia Milani Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: leticia.milani@neodent.com
Date of Revision:	June 30, 2026

Name of the Device

Trade Names:	Neodent Implant System - NeoConvert Fit
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

Traditional 510(k) Submission

Neodent Implant System - NeoConvert Fit

K261147 - 510(k) Summary

Predicate Device(s)

Primary Predicate:

K242686 Neodent Implant System

Reference Devices:

K163194 Neodent Implant System – GM Line

K170080 Neodent Implant System - CM Pro PEEK Abutment

Device Description

This premarket notification includes the NeoConvert Fit devices compatible with Neodent Implant System. The NeoConvert Fit devices proposed in this submission are similar to devices already cleared in previous submissions of Neodent Implant System, according to predicate devices described above.

The NeoConvert Fit is a technique that uses mini conical cylinders, a positioning cylinder and inserts to convert a removable temporary prosthesis into a screw-retained fixed temporary prosthesis on Grand Morse Implants (GM: K163194, K180536, K190718, K190958 and K201225) and Helix Short (HS: K223638) Implants. The submission includes the following devices: Mini Conical Abutment Cylinder, Positioning Cylinder, PEEK Insert, Titanium Insert, Recharger Sets (consisting of Mini Conical Abutment Cylinders, PEEK Inserts and screws) and Fit Case. Temporary protheses have a recommended maximum duration of usage of 180 days.

The NeoConvert Fit devices are compatible with the Mini Conica Abutments from GM and HS lines, as listed below:

Compatible Devices	510(k)
GM Mini Conical Abutment 30°	K133510
GM Mini Conical Abutment	K163194
GM Mini Conical Abutment 17°	
GM Mini Conical Abutment 30°	
GM Mini Conical Abutment 17° Rem. Screw	
GM Mini Conical Abutment 30° Rem. Screw	

Compatible Devices	510(k)
Neo Mini Conical Abutment Coping Screw	
GM Exact Mini Conical Abutment 45°	K190718
GM Exact Mini Conical Abutment 45° Rem. Screw	
GM Exact Mini Conical Abutment 60°	K203542
GM Exact Mini Conical Abutment 45° Slim	K232099
GM Exact Mini Conical Abutment 52°	
HS Mini Conical Abutment	K223638
HS Mini Conical Abutment 17°	
Neo Mini Conical Abutment Coping Screw	K242686

Indications for Use

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. The NeoConvert Fit Solution may be used with single-stage or two-stage procedures, for temporary 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 table:

Table 1 – Table of Substantial Equivalence NeoConvert Fit

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES		EQUIVALENCE DISCUSSION
K Number	-	***K242686*** ***Neodent Implant System***	***K163194*** ***Neodent Implant System – GM Line***	***K170080*** ***Neodent Implant System - CM Pro PEEK Abutment***	
Indications for Use	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. The NeoConvert Fit Solution may be used with single-stage or two-stage procedures, for temporary multiple-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	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. The NeoConvert Solution may be used with single-stage or two-stage procedures, for temporary multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	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.	The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.	**Identical** The proposed and primary predicate devices present the same indications for use, being both used onto dental implants to provide support for prosthetic restorations.
Material	Titanium alloy, according to ASTM F136. PEEK (Insert for Conversion)	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136. PEEK (GM Pro PEEK Abutment)	Titanium alloy, according to ASTM F136. PEEK	**Identical**
Surface treatment	Electrolysis		Electrolysis		**Identical**
Overall dimensions	Mini Conical Cylinder for Conversion: • Laying diameter: 4.8 mm • Height: 5.0 and 6.5 mm Positioning Cylinder for Conversion • Laying diameter: 4.8 mm • Height: 5.0 mm	NeoConvert Coping: • Laying diameter: 4.8 mm • Height: 5.0 and 6.5 mm NeoConvert Screw: • Laying diameter: 1.4 mm • Height: 3.7mm			**Similar** The positioning cylinder is similar in dimensions to the NeoConvert coping.
Single use	Yes	Yes	Yes	Yes	**Identical**

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICES		EQUIVALENCE DISCUSSION
K Number	-	***K242686*** ***Neodent Implant System***	***K163194*** ***Neodent Implant System – GM Line***	***K170080*** ***Neodent Implant System - CM Pro PEEK Abutment***	
Sterilization Method	Provided sterile via Ethylene Oxide and non-sterile. They must be terminally sterilized by user via moist heat cycle parameters validated to a SAL $1x10^{-6}$.	Provided sterile via Ethylene Oxide. The coping and screw, if opened and not used, must be terminally sterilized by user via moist heat with cycle parameters validated to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide.	Provided sterile via Ethylene Oxide.	**Similar** Although the proposed devices present a non-sterile commercial presentation, it must be sterilized via moist heat before installation, as the primary predicate device.

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”. The results demonstrated that in identical conditions, the subject devices exhibit a level of performance equal than the primary predicate device. Torsion test was 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.

MRI Compatibility Testing

An assessment was made to demonstrate that the MR conditional labeling (K260460) is applicable to the subject devices, and a patient treated with them can be safely scanned observing the parameters previously established per reference devices.

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*”.

The subject devices are identical in material, manufacturing processes, sterilization method, and packaging 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 supplied sterile via Ethylene Oxide (EO), the method was validated to a sterility assurance level (SAL) of $1x10^{-6}$ in accordance with ISO 11135:2014, "*Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*". EO sterilization residuals have been verified to be less than the maximum allowable limits as defined in ISO 10993-7 "*Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*".

The proposed devices that must be sterilized before installation in the mouth, the steam sterilization methos 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 is identical to the sterilization already cleared for the primary and reference predicate devices.

Shelf Life

The expiration date of the devices was determined considering the integrity of the product and the packaging tests after shelf-life testing. The material and packaging structure of the proposed abutments is equivalent to the primary predicate and reference devices. The shelf life for proposed devices is 5 years.

Conclusion

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