June 15, 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: K253922
Trade/Device Name: Neodent Scannable Healing Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 14, 2026
Received: May 14, 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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253922

Device Name
Neodent Scannable Healing Abutment

Indications for Use *(Describe)*
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.

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.

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Traditional 510(k) Submission

Neodent Scannable Healing Abutment

510(k) Summary

K253922

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 of Submission:	June 12, 2026

Name of the Device

Trade Names:	Neodent Scannable Healing Abutment
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Classification:	II
Product Code(s):	NHA
Classification Panel:	Dental

Traditional 510(k) Submission

Neodent Scannable Healing Abutment

510(k) Summary

K253922

Predicate Device(s)

Primary Predicate:

K163194 Neodent Implant System – GM Line (GM healings)

Reference Devices:

K212730 BellaTek Encode Emergence Healing Abutments

K182620 MRI Compatibility for Existing Neodent Implant System

Device Description

This premarket notification includes new scannable abutments of Neodent Implant System, which are compatible with GM prosthetic interface. The Neodent Scannable Healing Abutments proposed on this submission are similar to devices already cleared in previous submissions, according to predicate devices described above. This submission intends to expand the portfolio of Neodent Implant System with new solutions to provide more treatment options to the customers.

These proposed components are intended for temporary use, during the maintenance of soft tissues in the osseointegration phase of implants to be rehabilitated by the late loading technique. Additionally, they have the function of transferring the position and orientation of the implants position during intraoral scanning by means of the CAD/CAM technique. They are abutments to be placed out of occlusion.

Intended Use

The Neodent Scannable Healing Abutments are used for soft tissue maintenance, during the osseointegration phase of Neodent Implants to be rehabilitated by the late loading technique, and for the transfer of implant position during scanning by means of the CAD/CAM technique. It can be used in implant installation surgery or reopening surgery (second surgical phase).

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. 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:

Traditional 510(k) Submission

Neodent Scannable Healing Abutment

510(k) Summary

K253922

Table 1 – Table of Substantial Equivalence

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
K Number	***K253922*** ***Neodent Scannable Healing Abutment***	***K163194*** ***Neodent Implant System – GM Line (GM healings)***	***K212730*** ***BellaTek Encode Emergence Healing Abutments***
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. 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 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 BellaTek Encode Emergence Healing Abutments are intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration.
Material	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.	Titanium alloy, according to ASTM F136.
Interface Connection	Grand Morse (GM)	Grand Morse (GM)	N/A
Diameter	3.5, 4.5 and 5.5 mm	4.5 mm	3.5 to 5.7 mm
Gingival Height	0.8, 1.5, 2.5, 3.5, 4.5, 5.5 and 6.5 mm	0.8, 1.5, 2.5, 3.5, 4.5 and 5.5 mm	3.8 to 7.5 mm
Surface Treatment	Sandblasting + Electrolysis (yellow anodized)	Electrolysis (yellow anodized)	Electrolysis (pink anodized)
Scanning Identification	Encode coding scheme (machined markings) can be visualized in STL files.	N/A	Encode coding scheme (machined markings) can be visualized in STL files.
Single use	Yes	Yes	Yes
Sterilization Method	Provided sterile via Ethylene Oxide.	Provided sterile via Ethylene Oxide.	Provided sterile via Gamma Radiation.

Performance Testing

Bench Testing

A surface analysis was performed in line with FDA's guidance document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments", to characterize the surface topography using SEM (Scanning Electron Microscopy) and EDS (Energy Dispersive Spectroscopy). The detected chemical composition is consistent with titanium alloy (Ti6Al4V-ELI), with no significant variation among the samples. Samples also have a uniform morphology, and do not contain stains, debris, contamination, or manufacturing residues.

The anodization process applied to the subject device is exactly the same to that used for the primary predicate device (K163194), with no variation of parameters, formulation and equipments.

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.

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*".

To evidence the biological safety of subject devices, a cytotoxicity evaluation was conducted in accordance with ISO 10993-5 and ISO 10993-12, using the XTT method (inhibition of the cellular proliferation), after 72 hours of extraction time. Results ensure the biological safety of subject

devices per ISO 10993-1:2020 and FDA guidance, proving that the benefits provided by the device outweigh the residual risk of biological safety.

Sterilization validation

The subject devices are 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 sterilization of the subject devices is identical to the sterilization already cleared for the primary predicate device (K163194).

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 packaging of the proposed abutments is identical to the packaging of the primary predicate device (K163194). The shelf life for Neodent Scannable Healing Abutments is 5 years.

Clinical Testing

A prospective pilot clinical investigation evaluating the clinical performance and safety of the subject devices was conducted. The research was submitted and approved by local ethics committee, with the objectives of assessing marginal bone remodeling over time, as well as evaluating the peri-implant soft tissue parameters, clinical and esthetic outcomes as measured by the Pink Esthetic Score (PES) and the Visible Plaque Index (VPI). The study included 7 patients and 8 implants placed in posterior regions (4 maxilla and 4 mandible), in combination with 8 Neodent Scannable Healing Abutment. Teeth treated included premolars and molars.

Marginal bone remodeling was radiographically assessed at baseline, 90 days, 180 days, and after prosthetic loading. Results demonstrate a remodeling pattern consistent with the expected

physiological bone adaptation during early osseointegration and the establishment of the peri-implant biological width.

The Pink Esthetic Score (PES) assessment was conducted to assess the peri-implant soft tissue response and demonstrated the maintenance of peri-implant mucosal stability throughout follow-up. The parameters of soft tissue color, texture, and gingival contour were scored within ranges consistent with gingival health and showed no clinical evidence of inflammation. No clinical signs of mucosal breakdown, suppuration, or peri-implantitis were observed. No device-related or procedure-related adverse events were reported during the study period.

The plaque biofilm was evaluated by the Visible Plaque Index (VPI), assessed at baseline (before surgery), 90 days, 180 days, and post-loading (10 months after surgery). Results demonstrated a statistically significant reduction in plaque presence from baseline to 90 days. A statistically significant reduction was not demonstrated between all other timepoints. These findings indicate no increase in biofilm retention associated with the transmucosal roughened surface and no evidence of increased inflammatory burden. To support effective plaque control during the healing phase, patients enrolled in the clinical study were provided with standardized post-surgical oral hygiene instructions, which were effective and demonstrate adequate plaque removal from the abutment surface.

In addition, published clinical literature evidences were analyzed to support and demonstrate the consistence of results found in the pilot clinical study. Collectively, these characteristics evidence the safety and performance of the subject device under the proposed conditions of use, and the available evidence does not raise concerns regarding the risk associated with the device.

Conclusion

The subject, primary predicate and reference devices have similar indications for use, intended use, design, raw material and overall dimensions. The main technological difference of the subject devices, when compared to the primary predicate device (K163194) and reference device (K212730), is the sandblasted roughened transmucosal surface, which allows the abutment to be scanned. Surface analysis showed a composition consistent with the raw material (titanium alloy), and does not raise concerns on residual elements. These results are consistent with those found in biocompatibility tests, which demonstrated no cytotoxic response under the tested conditions.

Clinical evidence was also submitted to support the new surface technology safety for the intended indications. The prospective pilot clinical investigation evidenced results consistent with the published literature data. Together these data demonstrate the sandblasted roughened transmucosal surface does not adversely affect safety or effectiveness. Therefore, it is concluded that the proposed devices are substantially equivalent to the primary predicate and reference devices.