January 7, 2026

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

Re: K252727
Trade/Device Name: Neodent InLab Validated Workflow
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: December 3, 2025
Received: December 3, 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.	K252727

Please provide the device trade name(s).

Neodent InLab Validated Workflow

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 Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
The digitally designed personalized copings to be used with the Direct Connection Screw to Multi-Unit Abutment are to be:
• Sent to Straumann for manufacture at a validated milling center, or
• Manufactured following the Neodent InLab Validated Workflow.
The Neodent InLab Validated Workflow is indicated for the design and fabrication of screw-retained multi-unit restorations for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components: scan files from intra-oral scanners, CAD software, CAM software, milling machines and associated tooling and accessories.

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 InLab Validated Workflow

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:	Leticia Milani Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA
Date of Submission:	December 19, 2025

Name of the Device

Trade Names:	Neodent InLab Validated Workflow
Common Name:	Neodent InLab Validated Workflow
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Classification:	2
Primary Product Code:	NHA
Secondary Product Code:	PNP
Classification Panel:	Dental

Traditional 510(k) Submission

Neodent InLab Validated Workflow

510(k) Summary

Predicate Device(s)

Primary Predicate:

K242686 *Neodent Implant System*

Reference Devices:

K200100 *Abutment Design (3Shape)*
K193352 *AbutmentCAD (Exocad)*
K233252 *Straumann CARES Visual and Nova Dental CAD (CARES Visual)*
K182620 *MRI Compatibility for Existing Neodent Implant System*

Device Description

The purpose of this premarket notification is to obtain market clearance to expand the options for fabrication of digitally designed personalized copings for use with the Neodent Direct Screw to multi-unit abutment (MUA) from a “validated milling center” (cleared in K242686), to include a digital dentistry workflow.

The Neodent InLab Validated Workflow is integrated by multiple components of digital dentistry workflow: scan files from intra-oral scanners, CAD software, CAM software, milling machines and associated tooling and accessories. This new workflow employs optical impression files that document the topographical characteristics of teeth and traditional dental impressions, which are transferred to the CAD software (CARES® Visual, 3Shape or Exocad) and allows the design of the desired restorations, according to the Direct Screw to MUA dimensions. The CAM software converts the digital restoration design into the tooling and tool path commands needed to fabricate the restoration by the indicated milling equipments (Roland and Zirkonzahn).

Intended Use

The Neodent InLab Validated Workflow is intended for the design and manufacture of patient-specific screw-retained multi-unit restorations, for use with Direct Connection Screw to MUA. The Direct Connection Screw to MUA is intended to attach this customized multi-unit restoration to the prosthetic abutment (mini or micro 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. The Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

The digitally designed personalized copings to be used with the Direct Connection Screw to Multi-Unit Abutment are to be:

- Sent to Straumann for manufacture at a validated milling center, or
- Manufactured following the Neodent InLab Validated Workflow.

The Neodent InLab Validated Workflow is indicated for the design and fabrication of screw-retained multi-unit restorations for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components: scan files from intra-oral scanners, CAD software, CAM software, milling machines and associated tooling and accessories.

Technological Characteristics

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

Table 1 – Table of Substantial Equivalence

<table>
<tr><th>FEATURE</th><th>PROPOSED DEVICE</th><th>PRIMARY PREDICATE DEVICE</th></tr>
<tr><td>K Number</td><td>-</td><td>K242686
Neodent Implant System</td></tr>
<tr><td>Indications for Use</td><td>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 Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
The digitally designed personalized copings to be used with the Direct Connection Screw to Multi-Unit Abutment are to be:
• Sent to Straumann for manufacture at a validated milling center, or
• Manufactured following the Neodent InLab Validated Workflow.
The Neodent InLab Validated Workflow is indicated for the design and fabrication of screw-retained multi-unit restorations for the restoration of partially or fully edentulous mandibles and maxillae. The system integrates multiple components: scan files from intra-oral scanners, CAD software, CAM software, milling machines and associated tooling and accessories.</td><td>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 Direct Screw to MUA may be used with single-stage or two-stage procedures, for screw-retained multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. All digitally designed personalized copings to be used with the Direct to Multi Unit Abutment Screw are intended to be sent to Straumann for manufacture at a validated milling center.</td></tr>
<tr><td>Material</td><td>Direct Connect Screw to MUA:
Titanium alloy, according to ASTM F136</td><td>Direct Connect Screw to MUA:
Titanium alloy, according to ASTM F136</td></tr>
<tr><td>Overall dimension</td><td>Direct Connect Screw to MUA:
Diameter of the screw head: 2.2 mm
Height of screw head: 1.7 mm Total height: 4.1 mm</td><td>Direct Connect Screw to MUA:
Diameter of the screw head: 2.2 mm
Height of screw head: 1.7 mm Total height: 4.1 mm</td></tr>
<tr><td>Compatible implant prosthetic connection</td><td>GM, NGM and HS</td><td>GM, NGM and HS</td></tr>
<tr><td>CAD/CAM System</td><td>Validated Milling Center
Neodent InLab Validated workflow</td><td>Validated Milling Center</td></tr>
<tr><td>Commercially Supplied</td><td>Direct Connect Screw to MUA:
One cavity blister with five units</td><td>Direct Connect Screw to MUA:
One cavity blister with five units</td></tr>
<tr><td>Personalized coping restoration material</td><td>
<table>
<tr><th>Material</th><th>K number</th><th>Minimum thickness</th></tr>
<tr><td>N!ce® Zirconia HT</td><td>K222836</td><td>0.4 mm</td></tr>
<tr><td>N!ce® Zirconia LT</td><td>K222836</td><td>0.4 mm</td></tr>
<tr><td>N!ce® Zirconia XT</td><td>K222836</td><td>0.4 mm</td></tr>
<tr><td>Prettau®</td><td>K183304</td><td>0.4 mm</td></tr>
<tr><td>N!ce® PMMA</td><td>K071548</td><td>1.0 mm</td></tr>
</table>
*N!ce® PMMA is indicated to remain in the mouth only for up to 180 days
</td><td>
<table>
<tr><th>Material</th><th>K number</th><th>Minimum thickness</th></tr>
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<tr><td>N!ce® Zirconia LT</td><td>K222836</td><td>0.4 mm</td></tr>
<tr><td>N!ce® Zirconia XT</td><td>K222836</td><td>0.4 mm</td></tr>
<tr><td>N!ce® Titanium</td><td>Exempt according to 21 CFR 872.3710</td><td>0.4 mm</td></tr>
<tr><td>N!ce® Cobalt-Chromium</td><td>Exempt according to 21 CFR 872.3710</td><td>0.4 mm</td></tr>
<tr><td>N!ce® PMMA</td><td>K071548</td><td>1.0 mm</td></tr>
</table>
*N!ce® PMMA is indicated to remain in the mouth only for up to 180 days
</td></tr>
</table>

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE
K Number	-	***K242686*** ***Neodent Implant System***
Single use	Yes	Yes
Sterility	Provided non-sterile. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).	Provided non-sterile. Must be sterilized before installation via moist heat (steam), using either gravity or vacuum, with an exposure time of 3 minutes at 132°C (270°F).

Although the language is slightly different, the subject device has the similar indications for use to the primary predicate device, being both 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 main difference is the inclusion of Neodent InLab workflow for manufacture of digitally designed personalized restorations, as a new alternative for dentists, which is supported by the validation presented in performance tests section.

The Direct Screw to MUA itself remains with the same raw material, implant-to-abutment interface, design characteristics, packaging system and sterile condition cleared under K242686.

Performance Testing

Bench Testing

Assessments regarding dynamic fatigue testing and torsion 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”. Results demonstrated that in identical conditions, the subject devices exhibit a level of performance equal or better than the predicate and reference devices. Wear debris was also evaluated, based on SEM images made after fatigue loading test, to demonstrate that the personalized copings made from Zirconia and PMMA present acceptable levels of wear in the areas of the screw seating.

Software Validation

A software validation was carried out to simulate the usability and mitigate the risks of inaccurate milling of the Neodent InLab Validated Workflow applicable to Direct Connection Screw to MUA. The analysis was based on evaluating the dimensions of the restoration milled using the softwares and machines indicated, as well as on the verification that critical design parameters - such as minimum wall thickness and maximum angulation - are respected and properly monitored by the system. The results show that the data sent from CAD to CAM and milling machines generates accurate restorations that meet the design intent of the dental professional using the Neodent InLab Validated Workflow.

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*”.

Cytotoxicity tests were carried on the final device (Abutment + Direct Screw to MUA + Restoration (for both PRETTAU ZIRCONIA and N!CE ZIRCONIA), considering the detailed chemical composition of each raw material and the manufacturing process for the proposed validated workflow, including any materials introduced into the process. The results emphases that the final device does not present any additional risk to the patient.

Sterilization validation

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 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, intended use, design, raw material, overall dimensions and digital workflow. Thus, all documentation submitted in this premarket notification demonstrate that the proposed devices are substantially equivalent to the primary predicate.