August 2, 2021

JJGC Industria e Comercio de Materiais Dentarios S.A.
% Jennifer Jackson
Director of Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K203542
Trade/Device Name: Neodent Implant System - Mini Abutment 60°
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 2, 2021
Received: July 8, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203542

Device Name
Neodent Implant System - Mini Abutment 60°

Indications for Use *(Describe)*

The Mini Conical Abutments are indicated for use with Zygomatic Implants, in cases of severe jaw resorption, in order to restore patient aesthetics and chewing function. It may be used with single-stage or two-stage procedures, for 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.

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510(k) Summary
K203542

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Parana, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person	Jennifer M. Jackson, MS Director of Regulatory Affairs, Straumann USA E-mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	29/Jul/2021
Preparer / Alternate Contact	Mariana Soares Hartmann Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System - Mini Abutment 60°
Common Name	Endosseous dental implant
Classification Name(s)	Endosseous dental implant Abutment
Classification Regulation(s)	21 CFR 872.3630, Class II
Product Code(s)	NHA
Classification Panel Reviewing Branch	Dental Products Panel Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K190718 – Neodent Implant System – Zygomatic Implants and Abutments, JJGC Indústria e Comércio de Materiais Dentários SA

Reference Predicate Devices	K161598 – NobelZygoma 0°, Nobel Biocare AB K182620 - MRI Safety Information Labeling Change, JJGC Indústria e Comércio de Materiais Dentários SA

INDICATIONS FOR USE

The Mini Conical Abutments are indicated for use with Zygomatic Implants, in cases of severe jaw resorption, in order to restore patient aesthetics and chewing function. It may be used with single-stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

SUBJECT DEVICE DESCRIPTION

Mini Abutments 60°

- Intended for single use;
- Provided sterile via ethylene oxide gas;
- Manufactured of titanium alloy (Ti6Al4V-ELI) per ASTM F136;
- Available in different gingival heights;
- Screw-retained to the implant;
- Provided with an anti-rotational implant-to-abutment interface compatible with GM Zygomatic Implants;
- Provided with coronal geometries in rotational (non-indexed) versions to support multi-unit restorations
- The subject devices are compatible with Impression copings, Provisional cylinders, Protective cylinders and Copings of the Neodent GM Line previously cleared per market.

TECHNOLOGICAL CHARACTERISTIC COMPARISON

The Substantial Equivalence Comparison table is provided on the pages that follow below.

Table 1: Substantial Equivalence Comparison – Mini Abutments 60°

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE	EQUIVALENCE DISCUSSION
	Subject Mini Abutments 60° JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190718** Neodent Implant System – Zygomatic Implants and Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K161598** NobelZygoma 0° Nobel Biocare AB	
Indications for Use	The Mini Conical Abutments are indicated for use with Zygomatic Implants, in cases of severe jaw resorption, in order to restore patient aesthetics and chewing function. It may be used with single-stage or two-stage procedures, for multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	Zygomatic Implants are indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Zygomatic Implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Zygomatic Implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	NobelZygoma implants are end osseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	**Equivalent** Subject and primary predicate devices are indicated to be used together. The wording of the subject devices is a slightly different from the one of the primary predicate because the current submission is regarding abutments only and the predicate devices contained also implants in the submission.
Implant-to-Abutment Interface	GM	GM		**Identical** The implant-to abutment interface is equivalent to that of the primary predicate device.
Abutment Design	Gingival Height: 1.5; 2.5 mm Angulation: 60°	Gingival Height: 1.5; 2.5 mm Angulation: 45°	Gingival Height: 6; 8 mm Angulation: 45° and 60°	**Equivalent** The subject device gingival heights are equivalent to the primary predicate devices and the angulation is equivalent to the reference devices. Dynamic fatigue testing of the subject devices indicates performance suitable for the intended use.
Material	Titanium alloy (Ti6Al4V-ELI) per ASTM F136	Titanium alloy (Ti6Al4V-ELI) per ASTM F136	Titanium alloy (Ti6Al4V-ELI) per ASTM F136	**Identical** Subject and predicate devices have the same material of construction.

COMPARISON	SUBJECT DEVICES	PRIMARY PREDICATE	REFERENCE PREDICATE	EQUIVALENCE DISCUSSION
	Subject Mini Abutments 60° JJGC Indústria e Comércio de Materiais Dentários S.A.	**K190718** Neodent Implant System – Zygomatic Implants and Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K161598** NobelZygoma 0° Nobel Biocare AB	
Single Use	Yes	Yes	Yes	**Identical** Subject and predicate devices are not reusable.
Sterilization Method	Ethylene Oxide to a SAL of $1x10^{-6}$	Ethylene Oxide to a SAL of $1x10^{-6}$	Gamma radiation	**Identical** Subject and primary predicate devices utilize the same sterilization method and minimum SAL.
Compatible devices	GM Line Impression copings, Provisional cylinders, Protective cylinders and Copings already cleared per market.	GM Line Impression copings, Provisional cylinders, Protective cylinders and Copings already cleared per market.		**Identical** Subject and primary predicate devices are compatible with the same devices.

The subject devices have been assessed to determine whether the previously conducted studies related to the MR compatibility of the devices of the Neodent Implant System also apply to the subject devices. It has been determined that the subject devices do not result in new worst-case constructs for the purpose of assessing MR compatibility. 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 K182620.

SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Comparative dynamic fatigue test per ISO 14801 and FDA guidance was performed following the Zygomatic surgical protocol to determine the fatigue strength using the subject devices as compared to similar constructs of the reference devices.

Torsion testing was performed to evaluate the subject device's screws under static torsional loading. The results met the acceptance criteria.

Sterilization of the subject abutments via ethylene oxide gas was validated per ISO 11135. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated.

Ethylene oxide residuals have been assessed per ISO 10993-7. Residuals are within accepted limits.

Biological Safety Assessment guided by ISO 10993-1 and FDA guidance. Reference to previous biocompatibility testing is supplied as follows:

- Cytotoxicity testing was performed per ISO 10993-5.
- Chemical characterization was performed per ISO 10993-18.

Product and package stability has been validated per ASTM F1980. The subject device's shelf life was determined to be 5 years.

The MR Conditional Labeling was leveraged from K182620.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject devices are substantially equivalent to the legally marketed predicate devices.