November 9, 2019

JJGC Industria e Comercio de Materiais Dentarios SA
% Jennifer M. Jackson
Director Regulatory Affairs
Straumann
60 Minuteman Road
Andover, Massachusetts 01810

Re: K190958
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: October 10, 2019
Received: October 11, 2019

Dear Jennifer M. 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,

Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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)*
K190958

Device Name
Neodent Implant System

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. The Neodent GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

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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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor	JJGC Indústria e Comércio de Materiais Dentários SA (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 Director of Regulatory Affairs, Straumann USA E-Mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	08/Nov/2019
Preparer / Alternate Contact	Mariana Soares Hartmann Regulatory Affairs Analyst mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System
Common Name	Endosseous dental implant
Classification Name	Implant, Endosseous, Root-Form
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K160119, NobelSpeedy® Groovy, Nobel Biocare AB
Reference Devices	K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A K190718, Neodent GM Zygomatic Implants – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A

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 GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

SUBJECT DEVICE DESCRIPTIONS

The subject dental implant devices are single use devices, provided sterile by Gamma Radiation, made of commercially pure Titanium grade 4 (ASTM F67 – ISO 5832-2). The GM Helix LG Implant is a long conical implant with external diameters of 3.75 and 4.0 mm and lengths of 20, 22.5 and 25 mm. It has trapezoidal threads, conical apex with spherical tip and helical chambers, cylindrical body and Grand Morse prosthetic interface. The GM Helix LG implants share the same design characteristics as the existing GM Helix but are longer than the previously cleared range of implants. Indicated 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.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	**PRIMARY PREDICATE DEVICE**
	GM Helix LG (K190958) Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K160119** NobelSpeedy® Groovy Nobel Biocare AB
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 GM Helix LG implants can be placed bicortically in cases of reduced bone density. The Neodent GM Helix LG implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	NobelSpeedy® Groovy implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non- splinted applications. This can be achieved by a 2- stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bi-cortical anchorage in cases of reduced bone density NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.
Design	Threaded root-form implant with internal GM Morse taper connection with internal hex.	Single lead thread with groove, tapered apex with bone cutting flutes and external hex.
Device Material	Commercially Pure Titanium (ASTM F67)	Commercially Pure Titanium
Reusable	No	No
Platform Diameter	3.75; 4.0 mm	4.0 mm
Length	20; 22.5; 25 mm	20; 22; 25 mm
Surface	Machined, acid-etched NeoPoros surface.	TiUnite

Sterilization Method	Gamma Irradiation to an SAL of $1x10^{-6}$	Gamma Irradiation
Placement	Single or Bicortically in mandible or maxilla	Single or Bicortically in mandible or maxilla

SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject devices and the primary predicate device have equivalent intended use and Indications for Use statements. Both can be placed single or bicortically in mandible or maxilla. The subject devices and the primary predicate devices also share the same material of composition, the same sterilization method and range of length and present similar designs and platform diameter. The difference between the subject devices and the predicate devices is the Ø3.75 mm device. This change in technology is supported by the torsion test and pull out test, both included as appendices of this submission. The subject devices have the same thread design and the same implant-to-abutment interface design as the reference predicate devices.

PERFORMANCE DATA

Dynamic fatigue test per ISO 14801 was performed to determine the fatigue strength for implant construct assembled with prosthetic abutment for multi-unit prosthesis, assembled with GM Helix LG Implants, according to FDA Guidance.

Torsion Test was performed to evaluate the GM Helix LG Implant under static torsional loading. Insertion test was performed to evaluate the insertion torque of the GM Helix LG Implant when inserted into sawbones material representing bone type II, III and IV.

Pull-out testing was performed to compare the Axial Pull-out Strength between the subject devices and the predicate devices.

Sterilization of the subject implants via gamma irradiation using a protocol of 25 kGy minimum dose has been performed according to the requirements established by ISO 11137-1 and ISO 11137-2. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated.

Biological Safety Assessment guided by ISO 10993-1, Cytotoxicity guided by ISO 10993-5 and Chemical characterization guided by ISO 10993-18 were performed for GM Helix LG implants. Biocompatibility sample preparation was performed per ISO 10993-12.

CONCLUSION

The data included in this submission demonstrate that the subject devices are substantially equivalent to the predicate devices.