September 4, 2020

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

Re: K201225
Trade/Device Name: Neodent Implant System - GM Helix Implants 7.0
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: June 12, 2020
Received: June 15, 2020

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 Part 803) for devices or post-marketing 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,

for Srinivas Nandkumar, Ph.D.
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)*
K201225

Device Name
Neodent Implant System - GM Helix Implants 7.0

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 (21 CFR Part 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

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	03/Sep/2020
Preparer / Alternate Contact	Mariana Soares Hartmann Regulatory Affairs Analyst E-mail: mariana.hartmann@neodent.com

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Neodent Implant System – GM Helix Implants 7.0
Common Name	Endosseous dental implant
Classification Name	Endosseous dental implant
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	K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Predicate Devices	K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A K101201, KAT Implant System - KAT Implants LLC

K192221, Legacy2, Legacy3, Legacy4, SimplyLegacy2, SimplyLegacy3 Dental Implants; Legacy2, Legacy3, Legacy4 Fixture-Mounts, Implant Direct Sybron Manufacturing, LLC
K182620 - MRI Compatibility For Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A
K193592 - Neodent Implant System – Change in the Shelf Life of Neodent Acqua Implants

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.

SUBJECT DEVICE DESCRIPTIONS

- Intended for single use;
- Provided sterile via gamma irradiation;
- Manufactured of commercially pure titanium (Ti) grade 4 per ASTM F67;
- Morse Taper prosthetic interface with internal hexagonal indexer, exclusively from the Grand Morse (GM) line;
- Body center and apex with conical format;
- Trapezoidal-profile double threads;
- Rounded apex end;
- Available in Neoporos and Acqua surfaces;
- Ø7.0 mm and 8, 10, 11.5, and 13 mm lengths;
- The subject devices are compatible with all the abutments of the Neodent Implant System that present the GM implant to abutment interface, previously cleared per K163194, K173902, K180536, K191191, and K192229.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE	
	Neodent Implant System – GM Helix Implants 7.0 JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101201** KAT Implant System KAT Implants LLC	**K192221** Legacy4 Implant Direct Sybron Manufacturing LLC
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.	KAT Implant System Dental Implants are indicated for restoration of edentulous maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading is achieved. The implants can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.	Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 dental implants are two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. Narrow (3.2mmD) implants: Indicated for single-tooth replacement (mandibular central and lateral incisors; maxillary lateral incisors), multiple-tooth replacements or denture stabilization. Short (<10mm) 3.7mm implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization. The Legacy 2, Legacy3, and Legacy4 fixture-mounts are intended for use

<table>
<tr><th></th><th>SUBJECT DEVICE</th><th>PRIMARY PREDICATE DEVICE</th><th colspan="2">REFERENCE PREDICATE</th></tr>
<tr><td></td><td>Neodent Implant System – GM Helix Implants 7.0
JJGC Indústria e Comércio de Materiais Dentários S.A.</td><td>K163194
Neodent Implant System – GM Line
JJGC Indústria e Comércio de Materiais Dentários S.A.</td><td>K101201
KAT Implant System
KAT Implants LLC</td><td>K192221
Legacy4
Implant Direct Sybron Manufacturing LLC</td></tr>
<tr><td></td><td></td><td></td><td></td><td>with the corresponding dental implants (Legacy2, Legacy3, and Legacy4, respectively). The fixture-mounts can function as an abutment. As an abutment, fixture-mounts are intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous
patients.
Fixture-mounts as an abutment for narrow (3.2mmD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
Fixture-mounts as an abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and
maxillary central and lateral incisors.
Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 implants are compatible with the following abutments.
<table>
<tr><th>Manufacturer</th><th>Abutment Line</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Implant Direct</td><td>Legacy</td><td>3.0, 3.5, 4.5, 5.7</td></tr>
</table>
</td></tr>
<tr><td>Implant-Abutment interface</td><td>GM</td><td>GM</td><td>1.5° torque-activated locking taper connection</td><td></td></tr>
<tr><td>Design</td><td>Body center and apex with conical format
Rounded apex
Trapezoidal profile double threads</td><td>Body center and apex with conical format
Rounded apex
Trapezoidal profile double threads</td><td>Root-form implant;
Endosseous screw type with a continuous thread and horizontal circumferential fins</td><td>Body and apex straight, lower portion tapered with progressively deeper buttress-threads</td></tr>
</table>

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE	
	Neodent Implant System – GM Helix Implants 7.0 JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K101201** KAT Implant System KAT Implants LLC	**K192221** Legacy4 Implant Direct Sybron Manufacturing LLC
Reusable	No	No	No	No
Length (mm)	8; 10; 11.5; 13	8; 10; 11.5; 13; 16; 18	6; 8; 10	6; 8; 10; 11.5; 13; 16
Diameter (Ø) (mm)	7.0	3.5; 3.75; 4.0; 4.3; 5.0	6.0; 7.0. 8.0	3.2; 3.7; 4.2; 4.7; 5.2; 5.7; 7.0
Material	Commercially pure Titanium grade 4 (ASTM F67)	Commercially pure Titanium grade 4 (ASTM F67)	Titanium alloy (ASTM F136)	Titanium alloy
Sterilization Method	Gamma irradiation to a SAL of $1x10^{-6}$	Gamma irradiation to a SAL of $1x10^{-6}$	Gamma irradiation to a SAL of $1x10^{-6}$	Gamma irradiation

The subject devices and the primary predicate device K163194 have the same Indications for Use, the same design, similar range of lengths, same raw material and same sterilization method. The diameter of the subject devices is within the range of diameters of the reference predicate devices (K101201). The subject devices and reference predicate devices (K101201 and K192221) are indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

PERFORMANCE DATA

Biocompatibility

Biocompatibility sample preparation was made according to ISO 10993-12. Biological Safety Assessment guided by ISO 10993-1, Cytotoxicity testing was performed per ISO 10993-5 and Chemical characterization was performed per ISO 10993-18. The subject implants are made of unalloyed titanium, Grade 4, conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications* (UNS R50250, UNS R50400, UNS R50550, UNS R50700), the same type of titanium used for fabrication of the predicate devices cleared under K163194 and K180536. The subject devices undergo to the same manufacturing processes to the cited predicate devices. The subject devices do not present a new worst case for biocompatibility and therefore, the predicate and reference device testing are relied upon for determining substantial equivalence.

Mechanical testing

Dynamic fatigue test per ISO 14801 was performed to determine the fatigue strength for the dental implant system, according to FDA Guidance. The tested subject devices exhibit a level of performance equivalent to that reviewed for the predicate devices.

Insertion torque testing was also performed to determine insertion torque for the dental implants in Type III and Type IV bone.

Sterilization Validation

The subject implants are sterilized by ^{60}Co gamma irradiation at a nominal dose of 25 kGy (2.5 Mrad). Sterilization has been validated by the VD_{max}^{25} method, according to ISO 11137-1 and ISO 11137-2. The method achieved a Sterility Assurance Level 10^{-6}.

The Subject devices are not represented to be "pyrogen free". Routine endotoxin testing for NeoPoros and Acqua implants are performed monthly on representative samples of this group of products. The test limit is 20 EU/device as recommended by USP <161>.

The sterilization method presented for the subject devices is the same as for the predicate devices and has been previously reviewed under K163194 and K180536.

Shelf Life Validation

The subject implants have a shelf life of 5 years that was validated by accelerated aging according to ASTM F1980. The packaging was validated according to ISO 11607-1 and ISTA 2A. Sealing strength (ASTM F88), Dye Penetration (ASTM F1929), and Bubble Test (ASTM F2096) were conducted to verify the maintenance of the sterile barrier after storage.

CONCLUSION

The subject devices and the primary predicate devices K163194 have the same intended use, same design and technological characteristics, similar range of length, same sterilization method and are made of the same materials. The subject devices present a diameter that is contained within the range of diameters of the reference predicate devices. The data included in this submission demonstrate that the subject devices are substantially equivalent to the predicate devices.