July 11 , 2019

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: K190718
Trade/Device Name: Zygomatic Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 20, 2019
Received: March 20, 2019

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,

for Srinivas Nandkumar, Ph.D.
Acting Assistant 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)*
K190718

Device Name

Zygomatic Implants

Indications for Use *(Describe)*

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.

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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K190718

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	11/Jul/2019
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 – Zygomatic Implants and Abutments
Common Name	Endosseous dental implant Endosseous dental implant abutment
Classification Name	Implant, Endosseous, Root-Form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE/NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	K141777, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Predicate Devices	K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A K161598, NobelZygoma 0°, Nobel Biocare AB

INDICATIONS FOR USE

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.

SUBJECT DEVICE DESCRIPTIONS

The subject implant devices are single use devices, provided sterile by Gamma Radiation, made of commercially pure Titanium grade 4 (ASTM F67 – ISO 5832-2). The Zygomatic Implant is a long implant with an external diameter of 4.0 mm, conical apex, helical flutes, trapezoidal thread and GM prosthetic interface. Indicated for rehabilitation surgical procedures in atrophic maxilla cases, for installation in the zygomatic bone.
The subject abutment devices are single use devices, provided sterile by Ethylene Oxide, made of Titanium alloy (TI6AI4V-ELI). They are 45 degrees prosthetic abutments with anti-rotational feature, anatomic gingiva region and GM prosthetic interface to be installed on the implant, offering a structure to support the prosthesis. Indicated for rehabilitation of screw-retained bridges.

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	EQUIVALENCE DISCUSSION
	Neodent Implant System – Zygomatic Implants and Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**K141777** Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K161598** NobelZygoma 0° Nobel Biocare AB	
Indications for Use	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.	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 endosseous 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.	**Same** The subject devices and the primary predicate devices have the same Indications for Use.
Design	Threaded root-form implant to be used with matching abutments, made of titanium grade 4 45° angled abutments made of titanium alloy, intended exclusively for use with the GM Zygomatic implants	Threaded root-form implant to be used with matching abutments, made of titanium grade 4 Angled abutments made of titanium alloy	Tapered with cut out flutes 45° and 60° angled abutments made of titanium alloy	**Equivalent** For the predicate, the coronal aspect of the implant incorporated the 45˚ angle and the abutments were straight. For the subject devices, this is reversed. The subject abutments present the same angulation as the reference predicate devices K161598 (45°) The design of the subject device is equivalent to that of the reference device K163194.
Reusable	No	No	No	**Same**
Endosseous Diameter (mm)	4.0	4.4	4.5	**Equivalent** The difference is insignificant.
Length (mm) (Implants)	30; 35; 37.5; 40; 42.5; 47.5; 50; 52.5; 55	External hex: 30; 35; 40; 45; 47.5; 50; 52.5 Morse Taper: 30; 35; 40; 42.5; 45; 47.5; 50; 52.5	30, 35, 37.5, 40, 42.5, 45, 47.5, 50	**Equivalent** Similar range of sizes.

Gingival Height (mm) **(Abutments)**	1.5 and 2.5	1.5; 2; 3; 4; 5; and 6.	6, 8; 10	**Equivalent** Similar range of sizes, having the predicate the biggest range, covering the subject devices sizes.
Implant platform Ø (mm)	4.0	4.1	4.5	**Equivalent** The difference is insignificant.
Implant surfaces	Sand blasted, acid etched NeoPoros surface.	Sand blasted, acid etched NeoPoros surface.	TiUnite	**Same** The subject devices and the primary predicate devices present the same implant surfaces.
Sterilization Method	**Implants** Gamma Radiation to an SAL of $1x10^{-6}$	**Implants** Gamma Radiation to an SAL of $1x10^{-6}$	**Implants** Gamma Irradiation	**Same** The subject devices and the primary predicate devices present the same Sterilization Methods.
	Abutments Ethylene Oxide to an SAL of $1x10^{-6}$	**Abutments** Ethylene Oxide to an SAL of $1x10^{-6}$	**Abutments** Gamma Irradiation	
Sterile Barrier	**Implants** PET blister with Tyvek 1059B lidding	**Implants** PET blister with Tyvek 1059B lidding	**N/A**	**Same** The subject devices and the primary predicate devices present the same Sterile Barrier.
	Abutments PET blister with Tyvek 1059B lidding	**Abutments** PET blister with Tyvek 1059B lidding	**N/A**	

The subject devices and the primary predicate device K141777 have the same intended use and Indications for Use statements. The subject device and the primary predicate device K141777 have implants with similar platform and endosseous diameter, similar lengths, same surface treatment, same sterilization methods and same sterile barrier. The subject devices and the primary predicate device have abutments with similar range of Gingival Height, same raw material, same sterilization method and same sterile barrier.

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 Zygomatic Implants, according to FDA Guidance.

Torsion Test was performed to evaluate the GM Zygomatic Implant and the screw of GM Exact Mini Conical Abutment (45 Degrees) under static torsional loading.

Insertion test was performed to evaluate the insertion torque of the GM Zygomatic Implant when inserted into jawbones material representing bone type II, III and IV.

Sterilization of the subject implants via gamma irradiation using a protocol of 25 kGy minimum dose has been performed according to the requirements stablished by ISO 11137-2. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated. The sterility information and the sterile barrier validation was leveraged from K141777 for the implants.

Sterilization of the subject abutments via ethylene oxide gas using the overkill method has been performed according to the requirements of ISO 11135. A minimum Sterility Assurance Level (SAL) of 1×10^{-6} has been validated. The sterility information and the sterile barrier validation was leveraged from K163194 for the abutments.

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

Biological Safety Assessment guided by ISO 10993-1, was performed for GM Zygomatic and GM Exact Mini Conical Abutment.

Cytotoxicity testing was performed per ISO 10993-5.

Chemical characterization was performed per ISO 10993-18.

Biocompatibility sample preparation was performed per ISO 10993-12. The biocompatibility information for implants was leveraged from K141777 and for abutments was leveraged from K163194.

The MRI labeling was leveraged from K182620.

CONCLUSION

The subject device and the primary predicate device K141777 have the same intended use, have similar designs and technological characteristics, and are made of the same materials. The data included in this submission demonstrate that the subject device is substantially equivalent to the predicate device.