March 15, 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: K203382
Trade/Device Name: Neodent Implant System-Easy Pack
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 11, 2021
Received: February 12, 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 Steen
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)*
K203382

Device Name
Neodent Implant System - Easy Pack

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 GM Easy Pack System is indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K203382

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	15/Mar/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 – Easy Pack
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	Primary: DZE Secondary: NHA
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 Device	K191191 – Neodent Implant System – Temporary Abutments, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Predicate Device	K182620 - MRI Compatibility for Existing Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários S.A
Reference Predicate Device	K193592 - Change in the Shelf Life for Neodent Acqua Implants, 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 GM Easy Pack System is indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.

SUBJECT DEVICE DESCRIPTIONS

- Intended for single use;
- The subject GM Helix Implants are available in diameters of 3.5, 3.75, 4.0 and 4.3 mm and in heights of 8, 10, 11.5 and 13 mm;
- The subject GM Smart Abutments are available in diameters of 3.5 and 4.5 mm and gingival heights of 1.5, 2.5 and 3.5 mm. The GM Smart Abutments can be customized respecting a minimum post height of 4 mm. The GM Smart Abutments are being presented for the first time for FDA's evaluation;
- All digitally designed copings and/or crowns to be used with the GM Smart Abutments are intended to be sent to Straumann for manufacture at a validated milling center;
- The subject GM Healing Abutments are available in diameters of 3.5 and 4.5 mm and gingival heights of 1.5, 2.5 and 3.5 mm;
- Implant and Cover Screw delivered sterile via Gamma Radiation;
- Sterile Abutments provided sterile via Ethylene Oxide;
- The subject implant is manufactured of unalloyed titanium grade 4, according to ASTM F67;
- The GM Cover Screw, GM Smart Abutment, GM Healing Abutment and the Removable Screw are manufactured in titanium alloy Ti6Al4V-ELI according to ASTM F136;
- The GM Helix Implants, Acqua and Neoporos, the GM Cover Screw and the Healings subject of this submission are exactly the same devices already cleared to market per K163194;
- The GM Smart abutments, subject of this submission, are new abutments being introduced in this premarket notification;
- The implant to abutment interface is a Grand Morse (GM) connection.

The compatibility table for both GM Helix implants and GM Smart abutments is presented below (all combinations available within each row):

Implant Diameter	Implant Length	Abutment diameter	Abutment Gingival Heights
3.5 mm	8, 10, 11.5, 13 mm	3.5 and 4.5 mm	1.5, 2.5, 3.5 mm
3.75 mm	8, 10, 11.5, 13 mm	3.5 and 4.5 mm	1.5, 2.5, 3.5 mm
4.0 mm	8, 10, 11.5, 13 mm	3.5 and 4.5 mm	1.5, 2.5, 3.5 mm
4.3 mm	8, 10, 11.5, 13 mm	4.5 mm	1.5, 2.5, 3.5 mm

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLES

Table 1. Technological Characteristic Comparison Table – Implants and Cover Screw

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	
	Neodent Implant System – Easy Pack System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence Discussion**
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 GM Easy Pack System is indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.	<u>for GM implants and conventional abutments:</u> 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. <u>for GM Titanium Base abutments:</u> Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. <u>for GM Pro Peek Abutments:</u> The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.	**Similar** Subject devices and predicate devices share the same indications for use. The predicate for the subject implants and cover screw is the GM implants and conventional abutments of K163194. The temporary indication is covered by the GM Pro Peek Abutments of K163194.
Implant-Abutment interface	GM Morse Taper	GM Morse Taper	**Identical** Subject devices and predicate devices present the same Implant-to-abutment interface.

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	
	Neodent Implant System – Easy Pack System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence Discussion**
Implant Design	Conical shape, double threads with trapezoidal profile, rounded apex	Conical shape, double threads with trapezoidal profile, rounded apex	**Identical** Subject devices and predicate devices present the same design
Cover Screw Design	One end with a slot for the recommended driver/connection and the other end with an interface compatible with the GM prosthetic interface	One end with a slot for the recommended driver/connection and the other end with an interface compatible with the GM prosthetic interface	**Identical** Subject devices and predicate devices present the same design
Reusable	No	No	**Identical** The subject devices and the predicate devices are indicated for single use.
Implant Diameter (Ø) (mm)	3.5, 3.75, 4.0 and 4.3 mm	3.5, 3.75, 4.0, 4.3 and 5.0 mm	**Equivalent** Diameter of subject devices is within the range of diameters for the primary and reference predicate devices, so the subject devices do not represent a worst case in terms of performance.
Implant Length (mm)	8, 10, 11.5 and 13 mm	8, 10, 11.5, 13, 16 and 18 mm	**Equivalent** Range of lengths for subject devices is within the range of lengths for the primary and reference predicate devices.
Material	**Implant -** Titanium grade 4 conforming to ASTM F67 **Cover Screw -** Titanium alloy conforming to ASTM F136	**Implant -** Titanium grade 4 conforming to ASTM F67 **Cover Screw -** Titanium alloy conforming to ASTM F136	**Identical** Subject devices and predicate devices are manufactured of the same raw material
Surface	Neoporos Acqua	Neoporos Acqua	**Identical** Subject devices and predicate devices present the same surface
Sterilization Method	Provided sterile via Gamma Radiation to an SAL of $1x10^{-6}$	Implant - Provided sterile via Gamma Radiation to an SAL of $1x10^{-6}$ Cover Screw - Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$	**Equivalent** Subject devices and predicate devices are provided sterile by the same sterilization method. The subject Cover Screw provided along with the Implant is delivered sterile via Gamma Irradiation and when commercialized separately, provided sterile via Ethylene Oxide. Detailed information are provided in Section 14.

Table 2. Technological Characteristic Comparison Table - Abutments

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
	Neodent Implant System – Easy Pack System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K191191** Neodent Implant System – Temporary Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence Discussion**
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 GM Easy Pack System is indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.	<u>for GM implants and conventional abutments:</u> 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. <u>for GM Titanium Base abutments:</u> Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. <u>for GM Pro Peek Abutments:</u> The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.	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 - Temporary Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months.	**Similar** Subject devices and predicate devices share similar indications for use. Subject devices present the same indications for use as reference predicate devices (K191191).

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
	Neodent Implant System – Easy Pack System JJGC Indústria e Comércio de Materiais Dentários S.A.	**K163194** Neodent Implant System – GM Line JJGC Indústria e Comércio de Materiais Dentários S.A.	**K191191** Neodent Implant System – Temporary Abutments JJGC Indústria e Comércio de Materiais Dentários S.A.	**Equivalence Discussion**
Intended Use	GM Smart Abutment: Hybrid component that has three functions. It can be used as a scanbody, conventional closed tray transfer or temporary component. With scanbody function, the product is used to transfer the position and orientation of the implants to the digital model (scan) or plaster model (conventional). For use as a temporary component, the GM Smart Abutment is used for temporary rehabilitation (up to 180 days) with screw retrained single-unit protheses. The GM Smart Abutment is only used with implants placed straight (i.e no divergence) and is available in the GM prosthetic interface and must be used only with implants of corresponding interface.		The Temporary Abutment is used for temporary rehabilitation (up to 180 days) with screw retained single-unit (antirotational abutment) or multi-unit (rotational abutment) prostheses. Temporary Abutments are only to be used with implants placed straight (i.e. no divergence). This product is available in the GM prosthetic interface and must be used only with implants of corresponding interface.	**Similar** The scanbody and conventional closed tray transfer applications are exempt of registration, so it is not being considered in the comparison. The GM Smart Abutment application as temporary abutment is similar to the Temporary Abutment of K191191.
Implant-Abutment interface	GM Morse Taper	GM Morse Taper	GM Morse Taper	**Identical** Subject devices and predicate devices present the same Implant-to-abutment interface.
Reusable	No	No	No	**Identical** The subject devices and the predicate devices are indicated for single use.
Gingival Height (mm)	GM Healing Abutment - 1.5, 2.5 and 3.5 mm GM Smart Abutment - 1.5, 2.5 and 3.5 mm	GM Healing Abutment - 0.8, 1.5, 2.5, 3.5, 4.5, 5.5 mm	GM Temporary Abutments - 0.8; 1.5; 2.5 and 3.5 mm	**Equivalent** Range of size of gingival heights for subject devices is within the range of sizes for the primary and reference predicate devices.
Material	Titanium alloy conforming to ASTM F136	Titanium alloy conforming to ASTM F136	Titanium alloy conforming to ASTM F136	**Identical** Subject devices and predicate devices are manufactured of the same raw material
Sterilization Method	Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$	Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$	Provided sterile via Ethylene Oxide to an SAL of $1x10^{-6}$	**Identical** Subject devices and predicate devices are provided sterile by the same sterilization method.

The subject devices have the same indications for use as the primary predicate devices. They also present an equivalent range of lengths and diameter as the predicate devices, being contemplated within the range of lengths and diameter of the predicate devices.

Subject and predicate devices have the same implant-to-abutment interfaces. They present the same sterile barrier system and same sterilization methods. The subject devices and predicate devices are manufactured of the same materials.

Overall, the subject devices are equivalent to the predicate devices as follows:

- same intended use,
- same operating principle,
- incorporate the same basic design,
- incorporate the same materials, and
- have same packaging and are sterilized using the same materials and processes

NON-CLINICAL PERFORMANCE DATA

Sterilization

- **Gamma Radiation**
  The Gamma Radiation validation is based on the ISO 11137-2 Parts 1, 2 and 3. The purpose of this validation is to define the minimum dose Validation and Refer the Maximum dose approved by the client. The subject devices present the same sterilization method already validated for the predicate devices in K163194. The acceptance criteria is SAL of 10^{-6} with a Dose of 25 kGy and the result of the validation is passed.

- **Ethylene Oxide**
  The Ethylene Oxide validation is based on the ISO 11135:2014 Part 1. The purpose of this validation is to verify the maintenance of the effectiveness of the validated ethylene oxide sterilization process. The subject devices present the same sterilization method already validated for the predicate devices in K163194 and K191191.
  The acceptance criteria is SAL of 10^{-6} and the result of the validation is passed.
  EO sterilization residuals have been verified to be less than the maximum allowable limits as defined in ISO 10993-7 - *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*.

- **Steam Sterilization**
  The moist heat sterilization cycle (Dynamic air removal – 132 C, 3 mins, unwrapped) have been validated by the overkill method to a sterility assurance level (SAL) of 10^{-6} 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) and ISO 17665-2 (Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1). The subject devices present the same sterilization method already validated for the predicate devices in K163194. The acceptance criteria is SAL of 10^{-6} and the result of the validation is passed.

Shelf Life

- **Sealing Strength**
  The Sealing Strength test is based on ASTM F88 and the purpose of this test is to validated the packaging. The acceptance criteria is resistance between 1.5 N and 15 N for specimens with width of 15 ± 1 mm and the result of the test is passed.

- **Dye Penetration**
  The Dye Penetration test is based on ASTM F1929 and the purpose of this test is to validated the packaging. The acceptance criteria is no dye solution leakage through the blister sealing and the result of the test is passed.

- **Bubble Test**
  The Bubble test is based on the ASTM F2096 and the purpose of this test is to validated the packaging. The acceptance criteria is no constant flow of bubbles in the sealed area of the blister indicating a failure area and the result of the test is passed.

  The subject devices present the same shelf life already validated for the reference predicate devices in *K193592 - Change in the Shelf Life for Neodent Acqua Implants*. The shelf life for the Easy Pack System is 4 years.

Biocompatibility

- **Chemical Characterization**
  The Chemical Characterization is a test based on the ISO 10993-12 and ISO 10993-18 to identify extractable/leachable chemicals. The acceptance criteria is MOS > 1 or HI < 1 and the result of the test is passed.

- **Toxicological Analysis of Extractables**
  The Toxicological Analysis of Extractables is test based on the ISO 10993-17 to complement the Chemical Characterization test. The acceptance criteria is MOS > 1 or HI < 1 and the result of the test is passed.

- **Cytotoxicity**
  The Cytotoxicity is a test based on the ISO 10993-12 and 10993-5 to identify any substance with cytotoxicity potential. The acceptance criteria is cell viability ≤ 30 % and the result of the test is passed.

- **Corrosion Resistance**
  The Corrosion Resistance is a test based on ISO 10993-12 and ISO 10993-15 to evaluate the corrosion resistance. The acceptance criteria is the breakdown potential ≥ 0.8 V for implantable devices and the result of the test is passed.

- **Genotoxicity**
  The Genotoxicity is a test based on ISO 10993-12 and ISO 10993-3 to identify any substance with genotoxicity potential. The acceptance criteria is no biologically relevant increases in revertant colony numbers and the result of the test is passed.

  The subject devices do not present a new worst case for Biocompatibility. We are, therefore, relying upon testing performed previously on devices considered to be representative of the subject devices, already cleared per K163194.

Pyrogenicity

The pyrogenicity is a test based on ANSI/AAMI ST72:2011 to evaluate the pyrogenicity. The acceptance criteria is ≤ 0.5 EU/ml and the result of the test is passed.

The sampling frequencies were defined based on the criticality of the products and on historical results, as shown below:

Products	Quantity	Pool tested?	Frequency
Implants	10	Yes	Monthly
Abutments	10	Yes	Quarterly

The test is performed according to the turbidimetric kinetic method described in Chapter 85>Bacterial Endotoxins Test by United States Pharmacopeia and ANSI/AAMI ST72:2011 – Bacterial Endotoxins – Test Method, Routine Monitoring and Alternatives to Batch Testing.

The quantity of samples is defined by the two standards above.

The reports are being provided within this submission.

MRI

The MRI test is based on ASTM F2052, ASTM F2213, ASTM F2182 and ASTM F2119. The test has the purpose of characterization and behavior of the metallic implant system when subjected to the energy of a MRI scan. This study assesses magnetic migration, magnetic torsion, image aberration and RF-induced heating.

The acceptance criteria of each standard are as follow:

- ASTM F2052: maximum deflection angle, measured at the entrance of the bore of a 3T MRI of 45°
- ASTM F2213: the maximum MR induced torque must be less than the maximum torque induced by the force of gravity
- ASTM F2182: the mathematic model shall have a maximum deviation of ± 20% from the real measurement to confirm the model and the maximum temperature rise shall be less than 6°C.
- ASTM F2119: This test is for the purpose of characterization.

The results of the MRI is that a patient with an implant from a Straumann Group Implant System can be scanned safely in a MR System under the following conditions:

- Static magnetic field of 1.5T and 3T, only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the implants, as well as clinically relevant implant constructs, from a dental implant system of a Straumann Group company are expected to produce a maximum temperature rise of 4.9°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the implants from a dental implant system for a Straumann Group company extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3T MR system.

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 and they can be leveraged from the preciously cleared K182620.

Mechanical Tests

- **Torsion**
  The Torsion test is based on ISO/TS 13498:2011 and the purpose is to evaluate the static torsional loading. The acceptance criteria is 2.0 safety factor on the indicated torque on the IFU and the result of the test is passed.

- **Insertion**
  The Insertion test is based on ASTM F1839-08 and the purposed is to evaluate the implant presents minimum insertion torque in different situations.

  The complete reports regarding mechanical tests (Dynamic Fatigue Test, Torsion Test and Insertion Test) are being provided within this submission.

CONCLUSION

The subject devices and the predicate devices have equivalent Indications for Use, design and technological characteristics. Equivalent range of overall dimensions and sterilization methods. The data included in this submission demonstrate that the subject devices are substantially equivalent to the predicate devices.