JJGC Industria e Comercio de Materiais Dentarios SA
% Jennifer Jackson
Senior Manager, Regulatory Affairs & Quality Management
Straumann USA, LLC
60-100 Minuteman Rd
Andover, Massachusetts 01810

November 2, 2017

Re: K170080
Trade/Device Name: Neodent Implant System - CM Pro PEEK Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 25, 2017
Received: September 26, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170080

Device Name

Neodent Implant System - CM Pro PEEK Abutments

Indications for Use *(Describe)*

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.

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

Submitter	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 on behalf of: JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Olivera, 3291 Curtiba, Parana, BRAZIL 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person	Jennifer M. Jackson, MS Director, Regulatory Affairs & Quality, Straumann USA E-Mail: jennifer.jackson@straumann.com Telephone (978) 747-2509
Date Prepared	02/November/2017
Prepared by	Ana Carolina Martins Vianna RA & Compliance Manager, Institut Straumann AG ana.vianna@straumann.com
Product Code	NHA (21 CFR 872.3630)
Device Class	II
Classification Panel	Dental
Classification Name	Endosseous dental implant abutment (21 CFR 872.3630)
Common Name	Endosseous dental implant abutment
Proprietary name	Neodent Implant System – CM Pro PEEK Abutments
Primary Predicate Devices	K093027 – Straumann RC Temporary Abutments, Institut Straumann AG
Reference Devices	K101945 - Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA K133510 - Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA

5.1 Device Description

CM Pro PEEK abutments are temporary intermediary prosthetic components to be installed onto CM Implants to support the provisional prosthesis up to 6 months. They are composed of a customizable cylindrical body with an internal channel for the screw access and of a base for anti-rotational implant connection. The customizable portion is manufactured in PEEK (high performance polymer – specific for dental use) and the implant-to-abutment interface is made of titanium alloy. They have a coupled screw for fixing them to the Implant.

They present a hexagonal indexing at the apical end of the Morse taper connection to provide anti-rotational feature to the implant-to-abutment connection, and facilitates proper alignment of the prosthesis to the implant.

They are available in diameters of 4.5 and 6.0 mm and in lengths of 0.8, 1.5, 2.5, 3.5, 4.5 and 5.5 mm.

Figure 1: Model of CM Pro PEEK abutment

The customization of the PEEK chimney must be done into the mouth of patient or chairside. Chairside customization means that the device preparation must be done in a controlled environment in the operating room, in the context of the prosthetic placement, in a surgical site's aseptic environment using sterilized tools. The dentist can wear the height of the PEEK chimney with the aid of suitable techniques, high speed handpiece and cooling, according to the patient interocclusal space, respecting the minimum of 5mm of height. No customization is allowed for the diameter/ wall thickness of the abutment, as well as no angulation. No CAD/CAM design and fabrication is allowed for the CM Pro PEEK Abutments. Only hand-milling may be used for abutment modification.

The CM Pro PEEK abutments can be used before the installation of the final prosthesis to maintain, stabilize and shape the soft tissue (gum) during the healing phase.

5.2 Indications for Use

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.

5.3 Technological Characteristics

The temporary abutments made of PEEK are designed to be substantially equivalent to the predicate devices previously cleared per K093027.

The subject and predicate devices are based on the following same technological elements:

- Endosseous dental abutments to provide support for temporary restorations (primary predicate device);
- Possibility of use in single or two-stage procedures, for single or multiple-unit restorations (reference devices);
- Same sterilization methods and packaging (reference devices).

The following technological differences exist between the subject and predicate devices:

- Design of Morse taper implant-to-abutment interfaces;
- The subject abutment is provided sterile by EO exposition whereas its primary predicate device is provided non-sterile for end-user sterilization.

In the end of this Section, a comparison between the features of subject device and its predicate devices is shown in a tabular format. The assessment of the differences is also included.

5.4 Performance data

The following performance data supports the substantial equivalence determination:

<u>Biocompatibility testing</u>

The raw material PEEK used in fabrication of the CM Pro PEEK Abutments is the same of that cleared for the predicate device under K093027. Any difference in the biocompatibility posed by differences in the manufacturing process has been addressed by chemical characterization and cytotoxicity assessments. No extracts of leachable substances of concern were identified and no cytotoxicity response was observed.
The Biological Assessment has been performed according to ISO 10993-1 *Biological evaluation of medical devices. Evaluation and testing,* ISO 10993-5 *Biological evaluation of medical devices. Tests for in vitro cytotoxicity* and ISO 10993-18 *Biological evaluation of medical devices. Chemical characterization of materials*.

Mechanical testing

The strength of the CM Pro PEEK Abutment is demonstrated through fatigue testing performed according to ISO 14801 - *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* and FDA document *Guidance for Industry* and *FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*.

Sterilization validation

The subject abutments are sterilized by exposure to ethylene oxide (EO). Sterilization has been validated by the bioburden method, according to ISO 11135 *Sterilization of health care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices*. 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*.
All methods achieve a Sterility Assurance Level (SAL) of 10^{-6}.
The subject devices are not represented to be non-pyrogenic.

Shelf life was determined through both real time and accelerated aging protocol, according to ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*. After aging, samples were submitted to sterility test, thermal seal integrity test and tensile strength of thermal seal according to ISO 11737 - *Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility Performed in the definition, validation and maintenance of a sterilization process and US Pharmacopeia;* ASTM E499/E499M *Standard Practice for Leaks Using the Mass Spectrometer Leak Detector in the Detector Probe Mode,* ASTM F1929 *Standard Test Method for detecting Seal Leaks in Porous Medical Packaging by Dye Penetration* and ASTM F88/F88M *Standard Test Method for Seal Strength of Flexible Barrier Materials*.
The sterile barrier shelf life for the subject devices is 2 years.

Clinical data

No clinical data has been submitted, referenced, or relied upon to demonstrate substantial equivalence.

Table 1: Comparison between the subject and predicate devices.

	SUBJECT DEVICES	**PRIMARY PREDICATE DEVICES**	**REFERENCE DEVICES**		
	Neodent Implant System – CM Pro PEEK Abutment	Straumann RC Temporary Abutment **(K093027)**	Neodent Implant System **(K101945)**	Neodent Implant System **(K133510)**	**EQUIVALENCE DISCUSSION**
Indications for Use	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 Straumann RC Temporary Abutments are indicated for use in Straumann RC Bone Level Implants for temporary restorations of single crowns and bridges for up to six months	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. Multiple tooth applications may be rigidly splinted.	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. Multiple tooth applications may be rigidly splinted	**Equivalent** The Indications for Use for the subject and primary predicate devices are similar with the exception of minor wording differences. The intention to provide support to temporary restorations is the same. The subject device Indications for Use references the term “prosthesis structure” which is an overarching term that encompasses both crowns and bridges. The specific indication for immediate load when there is good primary stability is dependent on the implant Indications for Use. The implants also need to be indicated for immediate loading when good primary stability is achieved.

	SUBJECT DEVICES	**PRIMARY PREDICATE DEVICES**	**REFERENCE DEVICES**		
	Neodent Implant System – CM Pro PEEK Abutment	Straumann RC Temporary Abutment **(K093027)**	Neodent Implant System **(K101945)**	Neodent Implant System **(K133510)**	**EQUIVALENCE DISCUSSION**
Platform Diameter(s)	4.5 and 6 mm	4.5 mm	NA (only permanent abutments)	3.3 mm 4.1/4.3 mm 5.0 mm	**Equivalent** Subject device diameters are the same of the predicate devices or larger. Larger diameters do not represent a worst case in terms of performance.
Material	Titanium alloy Ti-6Al-4V ELI PEEK (polyetheretherketone)	Titanium alloy (Ti-6Al-7Nb, TAN) PEEK (polyetheretherketone)	Titanium Grade 4 Titanium alloy Ti-6Al-4V ELI	Titanium alloy Ti-6Al-4V ELI	**Equivalent** The subject and the predicate devices are made of the same type of raw material; the adequacy of the systems have been demonstrated via dynamic fatigue tests and biocompatibility assessment.
Implant-to-Abutment Connection	CM interface; 11.5° Morse taper with anti-rotational features.	Morse taper interface with anti-rotational features	CM interface; 11.5° Morse taper with anti-rotational features.	HE (external hexagon) interface	**Equivalent** The performance of each interface has been assessed by dynamic fatigue testing.

	SUBJECT DEVICES	**PRIMARY PREDICATE DEVICES**	**REFERENCE DEVICES**		
	Neodent Implant System – CM Pro PEEK Abutment	Straumann RC Temporary Abutment **(K093027)**	Neodent Implant System **(K101945)**	Neodent Implant System **(K133510)**	**EQUIVALENCE DISCUSSION**
Compatibility	Compatible with Neodent CM implants	Compatible with Straumann implants	Compatible with Neodent CM implants	Compatible with Neodent HE implants	**Equivalent** The interfaces of Neodent and Straumann devices are not interchangeable. Their performances are assessed respecting the fixtures compatibility.
Sterility	Delivered sterile by EO exposure.	Delivered non-sterile. To be sterilized by user before placed in patient mouth (moist steam sterilization).	Delivered sterile by EO exposure.	Delivered sterile by gamma irradiation.	**Equivalent** The sterilization method and posterior handling of the device is the same as the reference devices.

5.5 Conclusions

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified predicate devices.