



JJGC Industria e Comercio de Materiais Dentarios SA
% Jennifer Jackson
Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

January 18,2019

Re: K182620

Trade/Device Name: MRI Compatibility for Existing Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 19, 2018
Received: October 22, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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 -S3

Digitally signed by
Mary S. Runner -S3
Date: 2019.01.18
15:30:27 -05'00'

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

Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Devices

Indications for Use (Describe)

- HE (External Hex) implants, stock abutments and stock copings (originally cleared per K101207)
- Titamax CM (Cone Morse) implants, stock abutments and stock copings (originally cleared per K101945 and extended per K123022, K133696 and K150199)
- Titamax CM (Cone Morse) EX implants, stock abutments and stock copings (originally cleared per K101945 and extended per K123022, K133696 and K150199)
- Alvim CM (Cone Morse) implants, stock abutments and stock copings (originally cleared per K101945 and extended per K123022, K133696 and K150199)
- CM (Cone Morse) Drive implants, stock abutments and stock copings (originally cleared per K123022 and extended per K133696, K150182 and K150199)
- GM (Grand Morse) Titamax implants, stock abutments and stock copings (originally cleared per K163194)
- GM (Grand Morse) Drive implants, stock abutments and stock copings (originally cleared per K163194)
- GM (Grand Morse) Helix implants, stock abutments and stock copings (originally cleared per K163194)

The implants, abutments and copings of the Neodent Implant System are 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.

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)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Titamax WS Devices

Indications for Use (Describe)

- Titamax WS implants, abutments and copings (originally cleared per K123022)

The implants, abutments and copings of the Neodent Implant System are 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. The Neodent Implant System may be used for single or multiple unit restorations. Multiple tooth applications may be rigidly splinted.

The Titamax WS implants are indicated for a delayed loading protocol.

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)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Facility Devices

Indications for Use (Describe)

- Facility implants, stock abutments and stock copings (originally cleared per K123022 and extended per K133696 and K150199)

The implants, abutments and copings of the Neodent Implant System are 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. The Neodent Implant System may be used for single or multiple unit restorations. Multiple tooth applications may be rigidly splinted.

The Facility implants of the Neodent Implant System are indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures.

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)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Zygomatic Implant Devices

Indications for Use (Describe)

- Zygomatic implants, stock abutments and stock copings (originally cleared per K141777)

The Zygomatic implants, abutments and copings of the Neodent Implant System are 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 Zygomatic implants of the Neodent Implant System 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.

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)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Titanium Base Abutment Devices

Indications for Use (Describe)

- CM (Cone Morse) Titanium Base Abutment component of two-piece patient-specific abutment (originally cleared per K150367 and extended per K153624)
- GM (Grand Morse) Exact Titanium Base Abutment component of two-piece patient-specific abutment (originally cleared per K163194)

The implants, abutments and copings of the Neodent Implant System are 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 Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. The Titanium Base 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 are intended to be sent to Straumann for manufacture at a validated milling center.

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)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Titanium Base for CEREC Abutment Devices

Indications for Use (Describe)

- CM (Cone Morse) Titanium Base for CEREC Abutment component of two-piece patient-specific abutment (originally cleared per K160964)

The implants, abutments and copings of the Neodent Implant System are 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 Titanium Base for CEREC Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. They are 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 for CEREC Abutment are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

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)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Preface Abutment Devices

Indications for Use (Describe)

- CM Preface Abutment component of patient-specific abutment (originally cleared per K150367)

The implants, abutments and copings of the Neodent Implant System are 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 Preface Abutment is a titanium abutment to be used in fabricating a full custom abutment placed onto Neodent dental implants to provide support for customized prosthetic restorations. The Preface Abutments is indicated for screw-retained single restorations or cement-retained single or multi-unit restorations.

All digitally designed restorations for use with the Neodent Preface Abutment are intended to be sent to Straumann for manufacture at a validated milling center.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System ProPEEK Abutment Devices

Indications for Use (Describe)

- GM (Grand Morse) ProPEEK Abutments (originally cleared per K163194)
- CM (Cone Morse) ProPEEK Abutments (originally cleared per K170080)

The implants, abutments and copings of the Neodent Implant System are 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 Pro PEEK Abutment 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)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Orthodontic Anchor Devices

Indications for Use (Describe)

- Neodent Implant for Orthodontic Anchor (originally cleared per K102769)

The Neodent Implant for Orthodontic Anchor is a surgical device in the form of a temporary screw used as an aid in orthodontic movement procedures.

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)

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Indications for Use

510(k) Number (if known)

K182620

Device Name

MRI Compatibility for Existing Neodent Implant System Graft Screw Devices

Indications for Use (Describe)

- The Neodent Graft Screw (originally cleared per K103084)

The Neodent Graft Screw is an implantable device used for fixation of bone blocks for the regeneration of bone in the oral cavity. The product is intended for temporary use only.

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)

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