June 17, 2019

Straumann USA LLC
Loretta Kushner-Mooney
Sr. Director RA/QA NAM
60 Minuteman Road
Andover, Massachusetts 01810

Re: K190662
Trade/Device Name: MRI Compatibility for Existing Straumann Dental Implant Systems
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA, OAT, DZL
Dated: March 19, 2019
Received: March 20, 2019

Dear Loretta Kushner-Mooney:

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)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Modification to ITI DENTAL IMPLANT SYSTEM

ITI self-tapping implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

ITI DENTAL IMPLANT SYSTEM

ITI solid screw implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
ITI DENTAL IMPLANT SYSTEM

The ITI anterior implant is intended for surgical placement in the maxilla or mandible to serve as a base for prosthetic reconstructions. Specifically, the anterior implant is indicated for replacement of single lateral incisors in maxilla and lateral and central incisors in the mandible. It is particularly intended for those areas where the interdental space is extremely limited (minimum 5 mm) and where vestibulo-oral bone is restricted (minumum 5 mm). The anterior implant can also be used as a support for a full arch implant-borne restoration, but only in conjunction with a standard ITI 4.1mm dental implant.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
ITI DENTAL IMPLANT SYSTEM

ITI® tapered implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
PROSTHETIC ACCESSORIES TO THE ITI DENTAL IMPLANT SYSTEM

The abutment is placed in the dental implant to provide support for a prosthetic restoration such as a crown or bridge. The titanium temporary posts are screwed into the dental implants and serve as a base for a temporary prosthetic restoration. The plastic burn-out copings provide a cast inner surface for mating with the abutment and implant and are for use in casting restorations directly from porcelain-fused-to-metal alloy without the use of machined metal components. The healing cap and closure screw are titanium devices which are mounted onto the dental implant before the soft tissue is sutured in place around the implant and which are intended to protect the inner configuration of the implant. The healing cap also protects the outer 45 degree shoulder of the implant during the healing phase and helps stabilize and maintain the soft tissue.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
SYNOCTA ANGLED ABUTMENTS FOR THE ITI WIDE NECK IMPLANT

The ITI synOcta angled abutments for Wide Neck Implants are indicated for use in cases where the placement of an implant requires an angled reconstruction for an optimal result. The abutment can be used to restore crowns for single tooth replacements and bridges for multiple tooth restorations.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
ESTHETIC EASE ABUTMENTS FOR THE ITI DENTAL IMPLANT SYSTEM

Abutments are intended to be placed in the dental implant to provide support for a prosthetic restorations such as crowns or bridges. The ITI esthetic are indicated for cemented restorations in esthetic areas of the mouth. The abutment can be used to restore crowns for single tooth replacements and bridges for multiple tooth restorations.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
ABUTMENT AND PROSTHETIC ACCESSORIES TO THE ITI DENTAL IMPLANT SYSTEM

The abutment is placed in a dental implant to provide support for a prosthetic restoration such as a crown or bridge.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
ITI DENTAL IMPLANT SYSTEM

ITI® tapered implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

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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K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
ITI DENTAL IMPLANT SYSTEM

ITI® tapered implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The ITI Dental Implants are for single-stage or two-stage surgical 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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K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
DENTAL IMPLANT COPING (PROSTHETIC ACCESSORIES TO THE ITI DENTAL IMPLANT SYSTEM)

The device that is the subject of this submission is an angled titanium coping, which is a pre-manufactured component offering a pre-formed inner surface for mating with the dental implant abutment. The outer surface of the coping can be adapted to the individual restoration. The coping is angled and is used only with the ITI anterior implant.

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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

ITI SYNOCTA MESO ABUTMENTS

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The ITI provide synOcta Measo abutments and indicated for cemented restorations in esthetic areas of the mouth. The abutment can be used in single tooth replacements and tooth restorations.

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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K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
MODIFICATION TO ITI DENTAL IMPLANT SYSTEM

ITI implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. ITI Dental Implants are for single-stage or two-stage surgery.
ITI Dental Implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used.

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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

Straumann Dental Implant System

The ITI Dental System implants are for single-stage or two-stage surgical procedures. The ITI Dental System implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used in immediately loaded cases.

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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K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
The Straumann Ortho implant system

The Ortho implant of the Straumann Ortho system is an endosseous implant intended for placement in the mid-sagittal or promedion area of the hard palate or in retromolor positions. Its purpose is to provide a fixed anchorage point for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It is used temporarily and is intended to be removed ofter orthodontic treatment has been completed.
Ortho implants con be used in adults and juveniles (age 12 and older). In case of patients who have not yet completed skeletal growth (e.g. as shown by radiographic analysis of the hand/wrist), the ortho implant should be placed off the mid-line in the paramedian region of the palate in order to avoid the rnid-palatal suture.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Elliptic Matrix

The Elliptic Matrix is attached onto the Straumann Retentive Anchor abutment to provide support and retention for an overdenture.

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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Food and Drug Administration

Indications for Use

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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann Temporary Coping

The Straumann Temporary Coping is a coping intended to serve as a base for a temporary 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

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See PRA Statement below.

510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
RN SYNOCTA UCLA GOLD ABUTMENT FOR THE STRAUMANN DENTAL IMPLANT

Abutments are intended to be placed into dental bridges to provide support for prosthetic reconstructions such as crowns or bridges.

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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

RN SYNOCTA TEMPORARY MESO ABUTMENT

RN SynOcta Temporary Meso Abutments are for use in RN Straumann Dental Implants (04.8mm) for temporary restoration of single crowns in the anterior and posterior region for use up to six 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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN COMPUTER AIDED RESTORATION SERVICE

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The Straumann C.A.R.E.S. Titanium Abutment is indicated for cemented restorations. The abutment can be used in single tooth replacements and multiple tooth restorations.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann OrthoSytsem

The Straumann Palatal implant is intended for placement in the mid-sagittal or paramedian area of the hard palate or in retromolar positions. Its purpose is to provide a fixed anchorage point for the attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It is used temporarily and is intended to be removed after orthodontic treatment has been completed.
Palatal implants can be used in adults and juveniles age 12 and older. In case of patients who have not yet completed skeletal growth (e.g. as shown by radiographic analysis of the hand/wrist), the palatal implants should be placed off the mid-line in the paramedian region of the palate in order to avoid the mid-palatal suture.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann Dental Implants

Straumann Regular Neck and Narrow Neck implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used.
The Straumann Regular Neck Implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients for single-stage or two-stage surgery.
The Straumann Narrow Neck implants are intended for surgical placement in the maxilla or mandible to serve as a base for prosthetic reconstructions. Specifically, the Narrow Neck implant is indicated for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. It is particularly intended for those areas where the interdental space is extremely limited (minimum 5 mm) and where vestibule-oral bone is restricted (minimum 5 mm). The Narrow Neck implant can also be used as a support for a full arch implant-born restoration, but only in conjunction with a standard Straumann 4.1 mm dental implant.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN COMPUTER AIDED RESTORATION SERVICE (C.A.R.E.S.) CERAMIC COPING

Copings are intended to provide support for prosthetic reconstructions such as crowns or bridges. The Straumann C.A.R.E.S. Ceramic Coping is indicated for cemented restorations. The coping can be used in single tooth replacements and multiple tooth restorations.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
P.004 Implants

The P.004 Implants are intended for immediate, delayed or conventional placement in the maxilla and/or mandibular arches to support crowns bridges or overdentures in edentulous or partially edentulous patients.
They are intended for immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used.
Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. Mesa abutments are indicated for cemented restorations particularly in esthetic areas of the mouth. The abutment can be used in single tooth replacements and multiple tooth restorations.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
WN SYNOCTA GOLD ABUTMENT

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

P.004 RC TEMPORARY ABUTMENT P.004 TEMPORARY HEALING ABUTMENT (CAP)

P.004 RC Temporary Abutment is indicated for use in Straumann P.004 RC Bone Level implants for temporary restorations of single crowns and bridges for up to six months.
P.004 Healing Abutment, customizable (cap) is indicated for use in Straumann P.004 RC Bone Level implants to protect the inner configuration of the implant during the healing process. Maintains, stabilizes and forms the soft tissue and should be placed out of occlusion for up to six 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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN P.004 RC GOLD ABUTMENT

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and 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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
NARROW NECK TEMPORARY COPING

The Narrow Neck Temporary Coping acts as a basis for the fabrication of individual temporary restorations and small cemented temporary bridges on Straumann Standard Plus Implants 03.3mm Narrow Neck for use up to six 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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

P.004 NC ANATOMIC ABUTMENTS

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
P.004 HEALING ABUTMENTS AND CLOSURE SCREWS

P.004 Healing Abutments and Closure Screws are intended for use with the Straumann P.004 Bone Level Implant system to protect the inner configuration of the implant. Healing Abutments have a secondary function to maintain, stabilize and form the soft tissue during the healing process.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN P.004 RC GOLD ABUTMENT FOR BRIDGES

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and 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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
P.004 ABUTMENTS

Both the P.004 RC/NC Gold Abutment for Bars and RC/NC Titanium Abutment for Bars are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and 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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K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN P.004 CEMENTABLE ABUTMENTS TEMPORARY COPINGS AND PROTECTIVE CAPS

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.
Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.
Temporary Copings are intended to serve as a base for temporary restorations for up to 28 days.

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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Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
P.004 RC CARES TITANIUM AND CERAMIC ABUTMENTS

Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns or bridges. The P.004 RC CARES Titanium
Abutment is indicated for cemented restoration. The abutment can be used in single tooth replacements and multiple tooth restorations.
Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns or bridges. The P.004 RC CARES Ceramic
Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw retained.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
P.004 NC GOLD ABUTMENT FOR CROWNS

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and 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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K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
P.004 ABUTMENTS

P.004 NC Temporary Abutment is indicated for use in Straumann P.004 NC Bone Level implants for temporary restorations of single crowns and bridges for up to six months.
P.004 NC Healing Abutment, customizable is indicated for use in Straumann P.004 NC Bone Level implants to protect the inner configuration of the implant and maintains, stabilizes and forms the soft tissue during the healing process for us to six months and should be placed out of occlusion.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
SYNOCTA ABUTMENTS

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations.

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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

P.004 ABUTMENTS P.004 TEMPORARY COPINGS
P.004 PROTECTIVE CAPS P.004 PERMANENT COPINGS

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures. The subject abutments are for permanent screw-retained bridges and bar-retained implant-borne dentures.
Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.
Copings are intended to serve as a base for multi-unit bar or bridge restorations.
Temporary Copings are intended to serve as a base for temporary restorations 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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Device Name

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Indications for Use *(Describe)*

CEMENTABLE ABUNTMENTS; TEMPORARY COPINGS; PROTECTIVE CAPS

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.
Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.
Temporary Copings are intended to serve as a base for temporary restorations for less than 30 days.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
P.004 NC CARES TITANIUM AND CERAMIC ABUTMENTS

Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges and overdentures.
The P.004 NC CARES Titanium Abutment is indicated for cemented restoration. The abutment can be used in single tooth replacements and multiple tooth restorations.
The P.004 NC CARES Ceramic Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw retained.

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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

CONCAVE RN HEALING CAP

Healing Caps are intended for placement onto dental implants to protect the inner configuration and shoulder of the implant and to maintain, stabilize and form the soft tissue during the healing phase.

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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN DENTAL IMPLANT SYSTEM

Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following: extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

Specific indications for small diameter (0 3.3 mm) implants: Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in the molar region is not recommended.

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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN NN CARES TITANIUM AND CERAMIC ABUTMENTS

Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges and overdentures.
The Straumann NN CARES Titanium Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.
The Straumann NN CARES Ceramic Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained or directly veneered.

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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN WN CARES TITANIUM ABUTMENT

Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges or overdentures.
The Straumann WN CARES Titanium Abutment is indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN DENTAL IMPLANT SYSTEM

Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with
appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.
Specific indications for small diameter (0 3.3 mm) implants:
Because of their reduced mechanical stability; small diameter implants are only used in cases with a low mechanical load. Placement in the molar region is not recommended.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN MODIFIED DENTAL ABUTMENT

Abutments are used in connection with the prosthetic restoration of Straumann dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.
Modified Dental Implant Abutments are indicated for screw-retained single-tooth restorations and cement-retained single tooth and bridge restorations (via meso structures.)

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN DENTAL ABUTMENTS

The Straumann NC Temporary Abutments are indicated for use in Straumann NC Bone Level Implants for temporary restorations of single crowns and bridges for up to six 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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN RC TEMPORARY ABUTMENTS

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.

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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN CARES BRIDGE;
STRAUMANN CARES DOLDER BAR

The Straumann® CARES® Screw-Retained Bridge and Straumann® CARES® Dolder® Bar indicated for use as bars and bridges that attach to dental implants (Straumann RN (Regular Neck) 0 4.8 mm and WN (Wide Neck) 0 6.5 mm) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.
The Straumann CARES Screw-Retained Bridge can be designed for specific patient sizes and spans that are attached to 2 to 16 implants.
The Straumann CARES Dolder Bar can be designed for specific patient sizes and spans that are attached to 2 to 10 implants.

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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

NARROW CONNECTION STRAUMANN ANATOMIC IPS E.MAX ABUTMENTS

Abutments are used in connection with the prosthetic restoration of Straumann dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

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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Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN NARROW NECK CROSSFIT (NNC) 03.3MM DENTAL IMPLANT SYSTEM

Straumann® dental implants are suitable for the treatment of oral and endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.
Specific indications for small diameter (0 3.3 mm) implants:
Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in the molar region is not recommended.

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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Food and Drug Administration

Indications for Use

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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN CARES SCREW-RETAINED BRIDGE TITANIUM
STRAUMANN CARES DOLDER BAR TITANIUM

The Straumann® CARES® Screw-retained Bridge Titanium and Straumann® CARES® Dolder® Bar Titanium are indicated for use as bars and bridges that attach to dental implants (Straumann Regular Neck (RN) 04.8mm and Wide Neck (WN) 06.5mm) in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.
The Straumann® CARES® Screw-retained Bridge Titanium is available in different sizes and spans and can be fitted on 2 to 16 implants.
The Straumann® CARES® Dolder® Bar Titanium is available in different sizes and spans and can be fitted on 2 to 10 implants.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
NNC CEMENTABLE ABUTMENT STRAIGHT15 DEGREE ANGLE TYPE A 15 DEGREE ANGLE TYPE B
NNC BASAL SCREW CEMENTABLE ABUTMENTS

Abutments are used in connection with the prosthetic restoration of Straumann dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.
Narrow Neck CrossFit Cementable Abutments are indicated for cement-retained single tooth and bridge restorations.

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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

NNC SOLID ABUTMENT
NNC TEMPORARY COPING FOR SOLID ABUTMENT
NNC TEMPORARY CAP FOR SOLID ABUTMENT

Abutments are used in connection with the prosthetic restoration of Straumann dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.
Narrow Neck CrossFit Solid Abutments are indicated for cement-retained single tooth and bridge restorations.

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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

NNC Gold Abutment For Bridges

Abutments are used in connection with the prosthetic restoration of Straumann dental implants. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and 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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN CARES Variobase Abutment NNC
STRAUMANN CARES Variobase Abutment RN
STRAUMANN CARES Variobase Abutment WN ST

The Straumann® CARES® Variobase ™ Abutment is a two-piece dental abutment consisting of the Straumann® Variobase TM Abutment and the Straumann® CARES® Variobase™ Coping which is intended to be placed onto Straumann dental implants to provide support for prosthetic reconstruction such as crowns and bridges. Straumann® CARES® Variobase TM Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.
The Straumann® CARES® Variobase ™ Coping polycon® ae in combination with the Straumann® Variobase TM Abutment is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.

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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

BL 04.1 MM RC SLACTIVE 8MM TIZR AND 10MM 12 14MM

Straumann® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

Straumann Temporary Abutments VITA CAD-Temp

Straumann Temporary Abutments VITA CAD-Temp are indicated for use with Straumann Bone Level and Tissue Level implants for temporary crown and bridge restorations, and to maintain, stabilize and shape the soft tissue during the healing phase for up to six months, and should be placed out of occlusion.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
TL 04.1MM RNS SLActive TIZR 6 8 10 12 14 16MM Dental Implants

Straumann® dental Implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients (unless specific indications and limitations are present, as stated below). Straumann® dental Implants can also be used for Immediate or early Implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the Implants by the corresponding elements (abutments). When placing implants in the posterior region, we recommend using only large diameter implants. In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

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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510(k) Number *(if known)*

K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann Healing Abutments Healing Caps Closure Screws

Closure Screws, healing caps, and healing abutments, are Intended for use with the Straumann Dental Implant System (SDIS) to protect the inner configuration of the Implant and maintain, stabilize and form the soft tissue during the healing process.
Customizable healing abutments made of PEEK are for use for up to six 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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN Variobase Abutment NNC
STRAUMANN Variobase Abutment RN
STRAUMANN Variobase Abutment WN

The Straumann Variobase,. Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann Variobase. Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN CARES Bone Level Screw retained Bars
STRAUMANN CARES Bone Level Screw retained Bridges

Straumann CARES Screw-Retained Bridges and Bars are indicated for use as bars and bridges that attach to implants and/or to screw-retained abutments of the Straumann Dental Implant System (SDIS) to provide support for prosthetic reconstructions such as bridges and over-dentures. The final processed products have the purpose of restoring chewing function.
Straumann CARES Screw-Retained Bridges and Bars are indicated for screw retained restorations.

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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN Magellan(TM) Abutment Protective Cap Titanium Copings Gold Copings Basal Screw

The Straumann® Magellan TM abutments are indicated to be placed into Straumann® dental implants to provide support for prosthetic reconstructions such as crowns, bridges and bars.
The final processed devices have the purpose of restoring chewing function.
Magellan™ abutments are indicated for screw-retained restorations.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
STRAUMANN Cares Screw Retained Bars/Bridge

Straumann CARES Screw-Retained Bridges and Bars are indicated for use as bars and bridges that attach to implants and/or to screw-retained abutments of the Straumann Dental Implant System (SDIS) to provide support for prosthetic reconstructions such as bridges and over-dentures. The final processed products have the purpose of restoring chewing function.
Straumann CARES Screw-Retained Bridges and Bars are indicated for screw-retained restorations.

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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN Bone Level Tapered Implant

Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).

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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

STRAUMANN Bone Level NC Angeled Screw Retained Abutments

The Straumann® Screw Retained Abutments are indicated to be placed into the implants of the Straumann® Dental Implant System to provide support for prosthetic reconstructions such as crowns, bridges and bars.
The final processed devices have the purpose of restoring chewing function.
Straumann® Screw Retained Abutments are indicated for screw-retained restorations.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann Variobase Abutment NNC
Straumann Variobase Abutment RN
Straumann Variobase Abutment WN
Straumann Variobase Abutment NC
Straumann Variobase Abutment RC
IPS e.max CAD MO Coping IPS e.max CAD LT Crown IPS e.max CAD HT Crown coron CoCr Single Unit

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase™ Abutment system 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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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

Straumann Screw Retained Abutment

The Straumann® Screw-Retained Abutments are indicated to be placed into Straumann dental implants to provide support for prosthetic reconstructions such as crowns, bridges and bars.
The final processed devices have the purpose of restoring chewing function.
Straumann® Screw-Retained Abutments are indicated for screw-retained restorations.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann CARES Titanium Alloy (TAN) Abutment

The Straumann CARES® TAN abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/ screw-retained.

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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510(k) Number *(if known)*
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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann® Dental Implant System Roxolid® SLA Implants

Straumann dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth, Implants can be placed with immediate function on single-tooth and /or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).

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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510(k) Number *(if known)*

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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
NC Straumann Variobase Abutment for Bars/Bridges
RC Straumann Variobase Abutment for Bars/Bridges
NNC Straumann Variobase Abutment for Bars/Bridges RN
Straumann Variobase Abutment for Bars/Bridges WN
Straumann Variobase Abutment for Bars/Bridges

Straumann® Variobase™ prosthetic components directly connected to the endosseous dental implants are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration (bridge or over-denture) can be cemented on the Straumann® Variobase™ prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. They may not be placed into occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated.

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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K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
NC Straumann Screw Retained Abutments

The Straumann® Screw Retained Abutments are indicated to be placed into the NC and RC Bone Level implants of the Straumann® Dental Implant System to provide support for prosthetic reconstructions such as crowns, bridges and bars. The final processed devices have the purpose of restoring chewing function.
Straumann® Screw Retained Abutments are indicated for screw-retained restorations.

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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K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann Variobase CEREC

The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic
restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.
All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Sirona inLab software
(Version 3.65 or higher) or Sirona CEREC Software (Version 4.2 or higher) 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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann RN Gold Abutment for Bridge

Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

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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510(k) Number *(if known)*

K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Straumann Bone Level Tapered Implants

Straumann® Bone Level Tapered Implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann Bone Level Tapered Implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).

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

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510(k) Number *(if known)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

Straumann Sterile Healing Solution

Healing abutments, healing caps and closure screws are intended for use with the implants of the Straumann Dental Implant System to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process. Fixation caps are used to stabilize bone grafts in cases where bone augmentation is being performed in conjunction with implant placement.

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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

Straumann CARES Golden Ti/TiN Abutments

Abutments are placed into the dental implants to provide support for prosthetic restoration such as crowns, bridges or overdentures.
The Straumann CARES Golden Ti/TiN Abutments are indicated for single tooth replacements and multiple tooth restorations. The prosthetic restoration is cement-retained.

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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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

BLT 02.9mm SC SLA or SLActive RXD Loxim
SC Closure Cap and Healing Abutments
SC Temporary Abutments
SC Variobase Abutments SC CARES Abutment

Straumann® Bone Level Tapered Implants ∅2.9 mm are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and aesthetic oral rehabilitation of patients with missing teeth. Straumann® Bone Level Tapered Implants ∅2.9 mm can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth or multiple-tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding components (abutments).
The Straumann® Bone Level Tapered Implants ∅2.9 mm are indicated for reconstruction of missing incisors in the lower jaw and lateral incisors in the upper jaw.
Straumann® Closure Caps and Healing Abutments are indicated to be placed in the dental implant after placement in the patient's jaw to protect the inner configuration of the implant and to form, maintain and stabilize the soft tissue during the healing process. Closure Caps and Healing Abutments should be used only with the corresponding implant connection.
Straumann® SC Temporary Abutments are indicated for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. Straumann® SC Temporary Abutments have a maximum duration of usage of 180 days.
Straumann® SC Variobase® abutments are indicated for use as an aid in prosthetic rehabilitations. The prosthetic restoration can be cemented on the Straumann® SC Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and form the soft tissue during the healing phase. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.
Straumann® SC CARES® abutments are indicated for single-tooth replacements and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.

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

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K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

Straumann Screw Retained Abutments

Straumann Screw retained Abutments are indicated to be placed into the implants of the Straumann Dental Implant System to provide support for prosthetic reconstructions such as crowns, bridges and bars. The final processed devices have the purpose of restoring chewing function. Straumann Screw Retained Abutments are indicated for screw-retained restorations.

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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

ITI Distance System

This abutment system is intended to be used in conjunction with ITI endosseous dental implants to provide support for prosthetic devices (crowns, bridges, overdentures) for the functional and oral rehabilitation of edentulous or partially edentulous patients.

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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Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
MEMFIX

The Memfix Screws are intended to be used to temporarily stabilize and fixate autogenous bone grafts and/or non-resorbable barrier membranes used for regeneration of bone in the oral cavity.

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Titanium Healing Caps

Titanium healing caps are indicated for use with ITI Dental implants. They are used to allow the site to heal

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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510(k) Number *(if known)*
K190662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Angled Abutment

The modified angled abutment is indicated for use in cases where the placement of the implant requires an angled reconstruction for an aesthetic result. The abutment can be used to restore crowns for single tooth replacements and bridges for bound situations.
The angled abutment is not to be used in conjunction with the ITI 15 degree angled implant as the total degree of angulation is 30 degree or above.
The angled abutment is not to be used in conjuction with the Ø3.3 mm Solid Screw Implant for single, posterior restorations.

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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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)*

K190662

Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

Endosseous Dental Implant

Intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

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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Device Name

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Indications for Use *(Describe)*

Bonding Base

The bonding base is indicated for use with a standard ITI implant placed in the posterior oral cavity, to serve as a base for orthodontic attachment during orthodontic treatment.

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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Device Name

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Indications for Use *(Describe)*

Ortho Implant And Accessories

The Ortho implant of the Straumann Orthosystem is an endosseous implant intended for placement in the median palatal region or in retro-molar positions. Its purpose is to provide a fixed anchorage point for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It is used temporarily and is intended to be removed after orthodontic treatment has been completed.

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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Device Name

MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*

Synocta Prosthetics

Prosthetic accessories are used in conjunction with ITI dental implants in the prosthetic restoration of the implant. These prosthetic accessories include abutments, copings and cylinders, and transfer system components. Abutments are placed into the dental implants to provide support for prosthetic restorations such as crowns, bridges, and overdentures. Prefabricated copings and cylinders provide a machined or cast inner surface for mating with the abutment and implant, while the outer surface can be adapted to the individual restoration. Transfer system components are used in the process of transferring the situation in the oral cavity to a precise dental model. Protection caps are used to protect the outer configuration of the abutment and to maintain and condition the soft tissues during the prosthetic phase.

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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510(k) Number *(if known)*
K910662

Device Name
MRI Compatibility for Existing Straumann Dental Implant Systems

Indications for Use *(Describe)*
Synocta Angled Abutments

The synOcta® angled abutments are indicated for use in cases where the placement of the implant requires an angled reconstruction for an aesthetic result. The abutment can be used to restore crowns for single tooth replacements and bridges for bound situations.
The angled abutment is not to be used in conjunction with the ITI 15° angled implant as the total degree of angulation is 30 degrees or above.

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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