DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 17, 2017

Zimmer Dental, Inc.
Christina Boydston
Regulatory Affairs Manager
1900 Aston Ave.
Carlsbad, California 92008

Re: K160398
Trade/Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 14, 2017
Received: April 17, 2017

Dear Christina Boydston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Tapered Screw-Vent Zimmer Dental Implant

Zimmer dental implant systems are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer One-Piece (ZOP) Dental Implant

Zimmer One-Piece Implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor, and maxillary lateral incisor regions of partially edentulous jaws. The Zimmer One-Piece Implant must be splinted if two or more are used adjacent to each other. The Zimmer One-Piece Implant may be immediately restored with a temporary prosthesis that is not in functional occlusion

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Screw-Vent Zimmer Dental Implant

Zimmer Dental implant systems are designed for use in endentulous mandibles or maxillae for attachment of complete denture prostheses for immediate or conventional loading, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a free standing single tooth replacement.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Advent Zimmer Dental Implant

Zimmer dental implant systems are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

SwissPlus Dental Implant

Zimmer Dental implant systems are designed for use in endentulous mandibles or maxillae for attachment of complete denture prostheses for immediate or conventional loading, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a free standing single tooth replacement.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Spline Twist Dental Implant

Zimmer Dental implant systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses for immediate or conventional loading, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a free standing single tooth replacement.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Trabecular Metal Implant™ (Tapered Screw Vent® X Implant System)

Zimmer Dental implant systems are (Tapered Screw Vent® X Implant System) designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

The 3.7mmD Trabecular Metal Implants should be splinted to additional implants when used in the pre- molar region and should not be used in the molar region.

The 4.1mmD Trabecular Metal Implants should be splinted to additional implants when used in the molar region.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer 3.1mmD Dental Implants

The 3.1mmD Eztetic Dental Implants are designed for use in the anterior maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The 3.1mmD Eztetic Dental Implants may be placed immediately following an extraction or loss of natural teeth provided there is sufficient volume of alveolar bone to minimally support the implant (minimum 1mm circumferential and 2mm apical).

The 3.1mmD Eztetic Dental Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Dental Tapered Screw-Vent® T Implant, HA Coated & Zimmer Dental Tapered Screw-Vent® M Implant, HA Coated

Zimmer dental implant systems are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Dental Tapered Screw-Vent® T Implant & Zimmer Dental Tapered Screw-Vent® M Implant

Zimmer Dental implant systems are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Contour Hex-Lock Abutment, Straight

Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. Abutment can be used for a single or multiple-unit restoration.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Contour Hex-Lock Abutment, 17°

Abutment is used as a terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Abutment can be used for a single or multiple-unit restoration.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Dental Inc. Hex-Lock Abutment

Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. Abutment can be used for a single or multiple-unit restoration.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Hex-Lock Short Abutments

Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. Abutment can be used for a single or multiple-unit restoration.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Dental Inc. 20° Angled Abutment

Zimmer Dental Implant systems are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

"Cast-To" Gold Abutments, Engaging

Zimmer Dental Implant systems are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Cast-To Gold Abutment for the 3.1mmD Dental Implant System, Engaging

The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, Engaging is intended for use in the creation of a customized abutment for a cement-retained crown or bridge, or a customized screw-retained restoration.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

"Cast-To" Gold Abutments, Non-Engaging

Zimmer Dental implant systems are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Cast-To Gold Abutment for the 3.1mmD Dental Implant System, Non-Engaging

The Zimmer Cast-to Gold Abutments for the 3.1mmD Dental Implant System, Non-Engaging, is intended for use in the creation of customized multiple-unit restorations on implants (e.g., bars and bridges), when anti-rotation of the abutment is not necessary.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex

The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex are used for attachment of restorations requiring off-axis correction. The 2.9mm Angled Abutment and the 2.9mm Angled Abutment, Straight Hex are designed to be used in edentulous or partially edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement.

The 2.9mm Contour Abutment and the 2.9mm Contour Abutment, Straight Hex are used as a terminal or intermediate abutment for a cemented prosthesis. Abutment can be used for a single- or multiple-unit restoration. The 2.9mm Angled Contour Abutment and the 2.9mm Angled Contour Abutment, Straight Hex are designed to be used as a terminal or intermediate abutment for a cemented prosthesis where the angle needs to be offset by 17°. Abutment can be used for a single- or multiple-unit restoration.

The 2.9mm Temporary Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The 2.9mm Temporary Abutment can be used for cement-retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Angled Tapered Abutments, 15°

The Angled Tapered Abutment is used for a terminal or intermediate abutment for screw-retained multiple-unit restorations. The 30º Angled Tapered Abutment must be used within 45º of parallelism for a splinted restoration.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Angled Tapered Abutments, 30°

The Angled Tapered Abutment is used for a terminal or intermediate abutment for screw-retained multiple-unit restorations. The 30° Angled Tapered Abutment must be used within 45°of parallelism for a splinted restoration. The 15° Angled Tapered Abutment must be used within 30° of parallelism for a splinted restoration.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Dental Inc. Screw Vent Ball Abutment

Zimmer Dental implant systems are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Spline Temporary Abutment

Temporary Abutment, Engaging: Spline engaging titanium alloy cylinder with retentive parallel walls and a flared cuff. Attaches to the Spline Implant with a separate screw. For use when a temporary prosthesis for up to six weeks is desired. Single or multiple units. Do not use as a permanent abutment. Not to exceed six weeks of placement.

Temporary Abutment, Non-Engaging: Adjustable titanium alloy cylinder with retentive parallel walls and a cuff. Attaches to the Spline Implant with a separate screw. Does not engage the tines. For use when a temporary prosthesis for up to six weeks is desired. Single or multiple units.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Spline Fixed Abutment

For use as a terminal or intermediate abutment for cemented prosthesis. Abutments must be parallel to within 7.5° for Spline Implant or be prepped to be parallel. The Spline Abutments can be used for a single tooth or splinted to other abutments. Single use.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Spline Fixed Abutment, 17°

For use as a terminal or intermediate abutment for cemented prosthetics when long axis of abutment needs to be changed by 15°, 17° or 25°. Abutment can be used for single tooth or splinted restorations. Single use.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Zfx Titanium Abutment for NobelActive Implant System

The Zimmer Zfx Titanium Abutment for NobelActive Implant System is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment can be used with NobelActive and NobelReplace Conical Connection implants with a Narrow Platform (NP) Ø 3.5mm, or Regular Platform (RP) Ø 3.9mm.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Zfx Abutment for NobelReplace Implant System

The Zimmer Zfx Abutment for NobelReplace Implant System is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment can be used with NobelReplace, Replace Select and NobelSpeedyReplace implants with a Narrow Platform (NP) Ø3.5 mm, Regular Platform (RP) Ø 4.3 mm, WidePlatform (WP) Ø 5.0 mm or 6.0 Platform (6.0) Ø 6.0mm.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Zfx Titanium Abutment for Straumann Bone Level Implant System

The Zimmer Zfx Titanium Abutment for Straumann Bone Level Implant System is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment can be used with Straumann Bone Level implants with a Narrow CrossFit Platform Connection (NC) Ø 3.3mm or Regular CrossFit Platform Connection (RC) Ø 4.1mm or 4.8mm.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Zfx Titanium Base Abutment for Tapered Screw Vent Implant System

The Zimmer Zfx Titanium Base Abutment is a combination of a pre-manufactured (stock) abutment and Zimmer Zfx Abutment Coping or Crown as part of a straight or angled two piece abutment. The combination of the titanium base stock abutment and the abutment coping is designed for use as a terminal or intermediate abutment for cement or screw retained prostheses. The two-piece abutment is used for a single -unit or multi-unit(bridge) restoration. The Zimmer Zfx Abutment Coping shall be manufactured by an approved Zimmer Dental milling facility.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Zfx Abutment for Biomet 3i Certain Implant System

Titanium Abutment for Biomet 3i Certain Implant System is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment can be used with Biomet 3i internal connection implants with a 3.4mm, 4.1mm, 5.0mm, or 6.0mm Platform.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer® Patient Specific Abutment, Internal Hex, Titanium

The Zimmer Patient Specific Abutment, Internal Hex, Titanium is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit restoration.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Tapered Screw-Vent Healing Collar

The Healing Collar is used to assist in the forming of the soft tissue during healing before a final restoration is placed. The Healing Collar is for single use only.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

2.9mm Healing Collar

The Healing Collar is used to assist in the forming of the soft tissue during healing before a final restoration is placed. The Healing Collar is for single use only.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Zimmer Dental Surgical Cover Screw

The Healing Screw is used to seal the implant internal connection and separate it from the soft tissue which is sutured over the implant during healing. The Healing Screw and Surgical Cover Screw are for single use only.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

2.9mm Healing Screw

The Healing Screw is used to seal the implant internal connection and separate it from the soft tissue which is sutured over the implant during healing. The Healing Screw is for single use only.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K160398

Device Name: MRI Compatibility for Existing Zimmer Dental Implant Systems

Indications For Use:

Retaining Screw

The Retaining Screws are intended to be used for securing the temporary abutments, final abutments, and impression transfers to the implant or implant analog. The long Retaining Screw is intended to be used with Temporary Abutments for fabrication of screw-retained provisional restorations and with Impression Transfers for direct impressions.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)