September 24, 2021

Nobel Biocare AG
Bernice Jim
Head of RA Product Development and Marketed Products
P.O. Box, 8058 Zurich - Airport
Balsberg, Balz Zimmermann-Str. 7, Kloten 8302
SWITZERLAND

Re: K212125
Trade/Device Name: Nobel Biocare Dental Implant Systems Portfolio - MR Conditional
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 6, 2021
Received: July 7, 2021

Dear Bernice Jim:

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 Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelProcera Zirconia Implant Bridge (previously cleared per K202452)

The NobelProcera® Zirconia Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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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K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

TiUltra Implants and Xeal Abutments (previously cleared per K202344)

NobelActive TiUltra

NobelActive TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelActive TiUltra implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

NobelActive TiUltra 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

NobelActive TiUltra 3.0 implants are indicated for single-unit restorations only.

NobelReplace CC TiUltra

NobelReplace CC TiUltra implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function.

The NobelReplace CC TiUltra implants are indicated for single or multiple unit restorations. The NobelReplace CC TiUltra implants can be used in splinted or non-splinted applications. The NobelReplace CC TiUltra implant may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

NobelParallel CC TiUltra

NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function.

NobelParallel CC TiUltra implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

Implants with <7 mm length are for delayed loading only when appropriate stability has been achieved.

Remaining indications are continued on a separate page.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Indications for Use continued:

MUA Xeal:
The MUA Xeal is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
On1 Base Xeal:
The On1 Base Xeal device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. The On1 Universal Abutments consist of three major parts. Specifically, the On1 Base Xeal, the On1 Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow:
scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

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Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
On1 Universal Abutment (previously cleared by K181869)

The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. The On1 Universal Abutment consist of three major parts. Specifically, the On1 Base, the On1 Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-oral Scanners, CAD software, CAM software, ceramic material , milling machine and associated tooling and accessories.

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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K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
TREFOIL System (previously cleared per K172352)

The TREFOIL System is used to restore chewing function in fully edentulous mandibles. The three implants of the Trefoil Implants are placed between the mental foramina in fully edentulous mandibles in a 1-stage surgical technique combined with an immediate function loading protocol, provided sufficient primary stability for the selected technique is achieved. In cases where sufficient primary stability for two implants or more is not reached, the implants along with the Framework may also be used with an early or delayed loading protocol.

The following prerequisites must be fulfilled:
-Adequate quantity of bone (minimum height of 13 mm for 11.5 mm implant and 14.5 mm for 13.0implant and minimum width of 6-7 mm).
-Adequate mouth opening (minimum 40 mm) to accommodate the guided surgery instruments.
-Implant-supported prosthetics seated directly on dedicated 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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K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Healing Cap Multi-Unit Titanium (previously cleared per K171142)

The Healing Cap Multi-unit Titanium is a premanufactured prosthetic component to be directly connected to the dental abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure. Maximum intra-oral use is 180-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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K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
TREFOIL System (previously cleared per K170135)

The Trefoil system is used to restore chewing function in fully edentulous mandibles. The three implants of the Trefoil system are placed between the mental foramina in fully edentulous mandibles in a 1-stage surgical technique combined with an immediate function loading protocol, provided sufficient primary stability for the selected technique is achieved. In cases where sufficient primary stability of one or more implants is not reached, the implants along with the bar may also be used with an early or delayed loading protocol.
The following prerequisities must be fulfilled:

-Adequate quantity of bone (minimum width of 7 mm; and minimum heights of 13 mm for 11.5 mm implant and 14.5 mm for 13.0 mm implant)
-Adequate mouth opening (minimum 40 mm) to accomodate the guided surgery intruments.
-Implant-supported prosthetics seated directly on dedicated 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)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
On1 Concept (previously cleared per K161655)

The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelZygoma 0° (previously cleared per K161598)

Nobel Zygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Temporary Snap Abutment (previously cleared per K161435)

The Temporary Snap 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 Temporary SnapAbutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the Temporary Snap Abutment is not to exceed one hundred and eighty(180) 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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510(k) Number *(if known)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Multi-Unit Abutment Plus (previously cleared per K161416)

The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

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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K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelProcera HT ML FCZ Implant Bridge and Framework (previously cleared per K160158)

The NobelProcera HT ML FCZ (full contour zirconia) and framework Implant Bridge are indicated for use as a bridge anatomically shaped and/or framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
NobelSpeedy Groovy (previously cleared per K160119)

NobelSpeedy® Groovy implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.
NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bicortical anchorage in cases of reduced bone density.
NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restoration in splinted applications that utilize at least two 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
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
TREFOIL System (previously cleared per K152836)

The TREFOIL System is used to restore chewing function in fully edentulous mandibles.The three implants of the TREFOIL System are placed between the mental foramina in fully edentulous mandibles in a 1-stage surgical technique combined with an immediate function loading protocol, provided sufficient primary stability for the selected technique is achieved. In cases where sufficient primary stability for two implants or more is not reached, the implants along with the Framework may also be used with an early or delayed loading protocol.
The following prerequisites must be fulfilled:
-Adequate quantity of bone (minimum height of 13 mm and minimum width of 6-7 mm).
-Adequate mouth opening (minimum 40 mm) to accommodate the guided surgery instruments.
-Implant-supported prosthetics seated directly on dedicated 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
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
NobelZygoma 45° (previously cleared per K152093)

Nobel Biocare's Zygoma implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function. The Zygoma Implants may be put into immediate function provided that stability requirements detailed in the directions for use are satisfied.

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
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
NobelActive Wide Platform (WP) (previously cleared per K133731)

Nobel Biocare's NobelActive implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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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510(k) Number *(if known)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelProcera Overdenture Bar (previously cleared per K132749)

The NobelProcera Overdenture Bar is indicated for use as an overdenture bar that attaches to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelProcera Angulated Screw Channel Abutment Conical Connection (previously cleared per K132746)

The NobelProcera Angulated Screw Channel Abutment Conical Connection are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

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)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Nobel Biocare PEEK Abutments (previously cleared per K120954)

The Nobel Biocare PEEK Abutments are premanufactured prosthetic components directly connected to the endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelActive 3.0 (previously cleared per K111581)

The NobelActive 3.0 implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelActive 3.0mm (previously cleared per K102436)

The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelProcera Implant Bridge Zirconia (previously cleared per K091907)

The NobelProcera Implant Bridge Zirconia is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

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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K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelProcera Zi Abutments (previously cleared per K091904)

The NobelProcera Zi Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelProcera Ti Abutment (previously cleared per K091756)

The NobelProcera Ti Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

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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K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

NobelActive 8.5 mm & 18.0 mm (previously cleared per K083205)

Nobel Biocare's NobelActive implants are endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

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)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
NobelReplace Hexagonal Implants (previously cleared per K073142)

Nobel Biocare's NobelReplace Hexagonal Implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace Hexagonal Implants are indicated for single or multiple unit restorations. The NobelReplace Hexagonal Implants can be used in splinted or non-splinted applications. The NobelReplace Hexagonal Implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

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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K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
NobelActive Multi Unit Abutment (previously cleared per K072570)

NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

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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K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
NobelActive Internal Connection Implant (previously cleared per K071370)

Nobel Biocare's NobelActive implants are endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

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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K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Adapter PS (previously cleared per K063592)

Nobel Biocare's Adapter PS is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

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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K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Zygoma Angled Abutments (previously cleared per K052885)

The Nobel Biocare Zygoma Angled Abutment is intended to be used as a prosthetic component directly connected to the implant and is intended for use as an aid in prosthetic rehabilitation.

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

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Zygoma TiUnite (previously cleared per K050641)

Nobel Biocare's zygoma TiUnite is a titanium, endosseous implant with components intended to be placed in the upper jaw arch to provide support for prosthetic devices such as artificial teeth in order to restore patient esthetics and chewing function, Nobel Biocare's Zygoma TiUnite inclueds endosseous implants, a cover screw, healing abutments, and multi unit 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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K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Nobelspeedy Implants (previously cleared per K050406)

NOBELSPEEDY TM Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NOBELSPEEDY TM Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare NOBELSPEEDY TM Implants may be placed immediately to put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

NOBELSPEEDY TM Implants are indicated for use in soft bone or whenever immediate or early loading is applied. The NOBELSPEEDY TM Implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants. In addition, the NOBELSPEEDY TM Implants are preferred in these soft bone indications because bone formation on the TiUniteo surface is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration, and higher success rates.

NOBELSPEEDY TM Implants may be tilted up to 450. When used with angulations between 300 and 450 a minimum of four implants must be used and splinted.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Groovy Implants (previously cleared per K050258)

Nobel Biocare's Groovy Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's Groovy Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare Groovy Implants may be placed immediately to put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

Groovy implants are indicated for use in soft bone in posterior regions or whenever immediate or early loading is applied. The Groovy implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved 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
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Procera Implant Bridge, models 15-1001, 15-1002, 15-1051, 15-1052 (previouly cleared per K041236)

The Procera Implant Bridge is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The Procera Implant Bridge can be used at the implant or abutment level of the following implant systems: Nobel Biocare Brånemark System Nobel Biocare Replace SelectThe Procera Implant Bridge can be used at the implant level of the following implant systems: Nobel Biocare Replace Nobel Biocare Steri-Oss HL Nobel Biocare Novum Straumann Dental Implant System Regular neck 4.8 Straumann Dental Implant System Wide neck 6.5 The Procera Implant Bridge can be used at abutment level of the following implant systems: Nobel Biocare ARK abutment for Teeth-in-Hour concept.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Various Branemark System Implants-Immediate Function Indication previously cleared per K022562

The Branemark System implants are for single-stage or two-stage surgical procedures and cement or screw retained restorations. The Branemark System implants are intended for immediate placement and function on -single tooth and/or multiple tooth applications recognizing sufficient bone stability (type I or n bone) and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

BRANEMARK NOVUM previously cleared per K000018

The "Immediate Loading Treatment Protocol" is intended for use with selected Brånemark System Implants.These implants, when placed using the Immediate Loading Treatment Protocol, are indicated for use only in the anterior mandible between the mental foramina.

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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510(k) Number *(if known)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Amorphous Diamond Coated Screw (previously cleared per K992538)

The Amorphous Diamond Coated Screw is used to retain prosthetic components to dental implants or to other prosthetic components. The amorphous diamond coating will add a greater pre-load to the screw, which in turn help prevent the screw and prosthetic components from loosening.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Procera® Preparable Abutment System (previously cleared per K974150)

Nobel Biocare's Procera® Preparable Abutment System is a set of screw retained preparable abutments that are secured to an endosseous implant and are intended to function as an anchor to which prosthetic devices, such as artificial teeth, may be attached using dental cement to restore a patient's chewing function.

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)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
AurAdapt Abutment System (previously cleared per K972475)

Nobel Biocare's AurAdapt Abutment System is a set of screw retained modifiable gold alloy abutments which are secured to an endosseous implant and is intended to function as an anchor to which prosthetic devices, such as artificial teeth, may be attached using dental cement to restore a patient's chewing function.

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)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Branemark System - Zygomaticus Fixture System (previously cleared per K970499)

The Nobel Biocare Brallemark System - Zygomaticus Fixture System is an endosseous implant with components made of titanium intended to be placed in the upper jaw arch to provide support for prosthetic devices such as artificial teeth, and to restore the patient's chewing function. The system includes Fixtures, Drills, Hand Instruments, Cover Screws and Accessories.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Bio-Esthetic Indirect Abutment (previously cleared per K970073)

The intended use of Steri-Oss' Bio-Esthetic Indirect Abutment, an abutment retained with a lingual retaining screw, is to provide a stable, secure foundation upon which a prosthetic appliance (the purpose of which is restoration of masticatory function in the edentulous and partially edentulous patient) can be attached, yet remain retrievable.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Steri-Oss' Tiodized' screws (previously cleared per K964739)

The intended use for Steri-Oss' Tiodized' screws is the screw retained attachment of prosthetic components to one another and to dental 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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K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Replace Titanium Implant System (previously per K964220)

The implant is indicated for use in restoring masticatory function in the edentulous and/or partially edentulous patient.

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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K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
STERI-OSS GOLD ATTACHMENT SYSTEM (previously cleared per K963945)

Steri-Oss Gold Attachment System, the intended use of this device is for the screw retained attachment of prosthesis to abutments is for the screw and/or abutments to retained 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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

17° Angulated Abutment (previously cleared per K961736)

The Nobelpharma 17° Angulated Abutment is intended to be used in edentulous patients as an anchor to support a prosthesis

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

MirusCone Abutment System (previously cleared per K961728)

The Nobelpharma MirusCone Abutment System is intended to be used in edentulous patients as an anchor to support a prosthesis.

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)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Branemark System- Healing Abutment (previously cleared per K925779)

The Nobelpharma Branemark System- Healing Abutment is intended to be used as a temporary component to an endosseous implant to allow healing of 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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510(k) Number *(if known)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Branemark System Estheticone Abutment complete (previously cleared per K925777)

The Nobelpharma Branemark System - EsthetiCone Abutment Complete is intended to be used as a component to an endosseous 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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K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Branemark Systems - Titanium CoverScrew (previously cleared per K925771)

The Nobelpharma Branemark Systems - Titanium CoverScrew is intended to be attached to an endosseous implantprior to the first healing period to protect the innerthread of the fixture and prevent bone overgrowth.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Branemark System Abutment Complete (previously cleared per K925769)

The Nobelpharma Branemark System Abutment Complete is intended to be used as a component to an endosseous implant to support a prosthetic device.

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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K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Branemark System Temporary Solutions (previously cleared per K925766)

The Nobelpharma Branemark System Temporary Solutions are intended to be used in the same manner asthe permanent counterpart except that the former are usedto support transitional reconstructions.

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)*

K212125

Device Name
Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Branemark System Standard 3.75 mm Fixture (previously cleared per K925765)

All Nobelpharma fixtures for implant are indicated for use in the anterior and posterior regions of the maxilla and mandible. The fixtures are designed to support full arch reconstructions (fixed bridges and overdentures), partial arch reconstructions (fixed bridges) and single tooth replacement.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Brånemark System Self-Tapping Fixture (previously cleared per K925762)

The "Immediate Loading Treatment Protocol" is intended for use with selected Brånemark System Implants.These implants, when placed using the Immediate Loading Treatment Protocol, are indicated for use only in the anterior mandible between the mental foramina.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Titanium Plasma Spray Cylindrical Implant (previously cleared per K911592)

The Steri-Oss Titanium plasma sprayed cylindrical dental implant device are indicated for use in the mandible and maxilla for denture retention in the edentulous and partially edentulous patient.

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)*

K212125

Device Name

Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*

Angulated Abutment, Complete, Titanium SCDA102 (previously cleared per K905434)

Devices are used as connection with osseointegration fixtures.

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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