



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

April 11, 2016

Nobel Biocare AB
c/o Ms. Charlemagne Chua
Senior Regulatory Affairs Manager
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K152836
Trade/Device Name: TREFOIL System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA, DZI
Dated: March 2, 2016
Received: March 3, 2016

Dear Ms. Chua:

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,

 Tina Kiang -
S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K152836

Device Name
TREFOIL System

Indications for Use (Describe)

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

A.4. 510(k) Summary

I. SUBMITTER

Nobel Biocare AB
Vastra Hamngatan 1
Goteborg, SE-411 17
Sweden

Submitted by
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager
Phone: (714) 282-4800 x 7830
Fax: (714) 998-9348

Date Prepared: April 7, 2016

II. DEVICE

Name of Device: TREFOIL System
Common or Usual Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implant (21 CFR 872.3640)
Regulatory Class: II
Primary Product Code: DZE Other Product Code(s): NHA, DZI

III. PREDICATE DEVICE

Primary predicate:
Nobel Biocare – Branemark Novum (K000018)
This predicate has not been subject to a design-related recall.

Reference predicates:
Nobel Biocare – NobelActive (K142260)
This predicate has not been subject to a design-related recall

Nobel Biocare – NobelProcera Overdenture Bar (K132749)
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION

The TREFOIL System is a method of placing three dental implants in predetermined positions (between the mental foramina) and using a pre-designed prosthetic bar to act as a screw-retained framework seated on the implants. The TREFOIL System restores chewing function and esthetics in the mandible in completely edentulous patients.

The TREFOIL System consists of dental implants, surgical components necessary to place the implants in predetermined positions, and prosthetic components that are included in the prosthetic bar or are used in the dental lab during the creation of the prosthetic bar.

The dental implants are threaded endosseous implants made of CP4 titanium. The implant is parallel walled and has an internal conical abutment connection. The implant is available in 11.5 mm length with two available collar lengths (4.5, 6.0 mm). The apex of the implants have cutting chamber allowing for self-tapping. The implant bone interface has the TiUnite implant surface treatment. The TREFOIL System bar is made of titanium vanadium alloy. The TREFOIL System surgical tooling is made of stainless steel.

V. INDICATIONS FOR USE

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 13mm and minimum width of 6-7mm).
- Adequate mouth opening (minimum 40 mm) to accommodate the guided surgery instruments.
- Implant-supported prosthetics seated directly on dedicated implants

VI. Comparison of Technological Characteristics

Comparison of indication for use statement

| | Subject Device | Primary Predicate |
|--|---|---|
| | TREFOIL System | Branemark Novum (K000018) |
| Indication for use statement | <p>The TREFOIL System is used to restore chewing function in fully edentulous mandibles.</p> <p>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.</p> <p>The following prerequisites must be fulfilled:</p> <ul style="list-style-type: none"> - Adequate quantity of bone (minimum height of 13mm and minimum width of 6-7mm). - Adequate mouth opening (minimum 40 mm) to accommodate the guided surgery instruments. - Implant-supported prosthetics seated directly on dedicated implants | <p>Totally edentulous mandibles with a minimum height of 13 mm and a minimum width of 6mm. Patient must be subject to dental treatment with endosseous implants. For use in a single stage procedure where the implants are immediately loaded.</p> |
| <p><u>Comparison of Indications for Use:</u> The intended use of the TREFOIL System is substantially equivalent to the Branemark Novum (K000018) predicate. The prerequisites for minimum bone height and minimum bone width remain the same, while the TREFOIL System provides additional safety prerequisites for mouth opening minimum size and implant supporting of seated prosthetics. Additional safety considerations from the labeling of the Branemark Novum (K000018) predicate have been added to the indications for use of the TREFOIL System regarding number of implants for placement, functional loading, and primary stability, which do not affect the intended use.</p> | | |

Implant Comparison

| Technological characteristics | | Subject Device | Primary Predicate | Reference Predicate |
|-------------------------------|----------------------|--|---|---|
| | | TREFOIL System | Branemark Novum (K000018) | NobelActive (K142260) |
| Implant Design Features | Implant Body Design | Parallel walled | Parallel walled | Expanding Taper |
| | Implant Tip Design | Tapered self cutting 3.8 mm apex w/9.5° angle | Tapered self cutting with through hole 3.5 mm apex w/15° angle | Drilling blades on apex 5.35 mm apex |
| | Implant Length | 16.0 mm overall (11.5 mm body w/ 4.5 mm collar) 17.5 mm overall (11.5 mm body w/ 6.0 mm collar) | 17.5 mm overall (11.5 mm body w/ 6.0 mm collar) | 6.5, 8, 9.5, 11, 12.5 mm |
| | Implant Diameter | 4.93 mm | 5.0 mm | 5.5 |
| | Platform Diameter | 4.5 mm | 4.5 mm | 5.5 |
| | Thread angle/pitch | 60°/.8mm | 60°/.8mm | variable |
| | Connection Type | Internal Hex with snap feature | External hex | Internal Hex |
| | Device Material | CP titanium | CP titanium | CP titanium |
| | Surface modification | TiUnite (anodic oxidation) | Machined titanium | TiUnite (anodic oxidation) |

Framework Bar Comparison

| Technological characteristics | | Subject Device | Primary Predicate | Reference Predicate |
|-------------------------------|-------------------------|--|--|--|
| | | TREFOIL System | Branemark Novum (K000018) | NobelProcera Overdenture Bar (K132749) |
| Bar Design Features | Bar Design | Preshaped single piece design screw retained to implant. | Preshaped two piece design. Lower bar screw retained to implants directly. Upper prosthetic bar screw retained to lower bar. | Individually shaped screw retained single bar design made to order. |
| | Intended platform | TREFOIL implant (intenal conical connection with snap fit) | Branemark Novum implant (external hex) | Various implant platforms (see K132749 summary) including Nobel Biocare conical connection |
| | Materials | Titanium vanadium alloy | CP titanium | Titanium vanadium alloy |
| | Surface modification | Machined titanium | Machined titanium | Machined titanium |
| | Compensation mechanism | Round abutment and corresponding framework and screw disks | Implant collar partially shaped by pre-torquing technique. | N/A |
| | Prosthetic media | Acrylic | Acrylic | Acrylic |
| | Fixed cantilever length | 18.8 mm | 19.7 | N/A |

Surgical Tooling Comparison

| Technological characteristics | | Subject Device | | Predicate | |
|-------------------------------|-------------------|----------------|--|--|--|
| | | TREFOIL System | | Branemark Novum (K000018) | |
| Surgical tooling type | Drill | Diameter | 2.0, 3.0, 3.8, 4.0, 4.2, 4.4 mm | 2.0, 2.5, 3.0, 3.5, 3.8, 4.0, 4.2, 4.3, 4.4 mm | |
| | | Flute length | 16.0 mm (including tip) | 18.0, 24.0 mm (excluding tip) | |
| | | Material | Stainless Steel DIN EN 10027-2 – 1.4197 DLC coated | Stainless Steel 440F Hardened to MN 500 HV2 No coating | |
| | | Connection | ISO 1797 Type 1 | ISO 1797 Type 1 | |
| | | Markings | All drills marked at 11.5 mm and 13.5 mm | 18.0 mm length single marked for 11.5 mm implant thread 24.0 mm length marked for both 11.5 mm implant thread | |
| | | Flute design | Two flutes | Three flutes | |
| | | Tip design | 90° (2mm) 130° (3.0, 3.8, 4.0, 4.2, 4.4 mm) | 120° | |
| | | Intended use | The drills are used together with corresponding Templates for drills for the preparation of the implant sites. | The drills are used together with corresponding Templates for drills for the preparation of the implant sites. | |
| | Screw Tap | Flute length | 17.0 mm | 15.5 mm | |
| | | Diameter | 5.0 mm | 4.5 mm | |
| | | Materials | Stainless Steel DIN EN 10027-2 – 1.4197 DLC coated | Titanium vanadium alloy | |
| | | Connection | ISO 1797 Type 1 | 2.4 mm square | |
| | | Intended use | The screw tap is used when dense bone is present to prepare for the threaded implant | The screw tap is used when dense bone is present to prepare for the threaded implant | |
| | Stabilizing screw | Core diameter | 1.8 | 1.8 | |
| | | Length | 14.0 mm (to stop) 19.3 mm (overall) | 13.0 mm (to stop) 20.0 mm (overall) | |
| | | Materials | 316 Stainless Steel | 316 Stainless Steel | |
| | | Intended use | The stabilizing screw is used to temporarily connect the V-template to the alveolar ridge | Short and long screws used to stabilize the V-gage template to the alveolar ridge | |

VII. PERFORMANCE DATA

Laboratory testing was performed to establish the accuracy of the TREFOIL System surgical protocol. This testing included placement of the Trefoil implants into bone models following the Trefoil Instructions for Use and utilizing Trefoil surgical tooling. The results were evaluated by cone beam computed tomography. This testing established the angular and translational accuracy errors generated by the surgical procedure.

The ability of the Trefoil framework compensation mechanism to adapt to the expected angular and translational accuracy errors generated by the surgical procedure was established through the use of three-dimensional modeling. The modeling confirmed that the Trefoil compensation mechanism will ensure a passive fit of the framework bar on the Trefoil implants.

Fatigue testing was performed to establish that the TREFOIL System will withstand foreseeable mastication forces. Fatigue testing was done by using a test scenario developed for splinted implant applications. Fatigue testing was conducted and results analyzed in accordance with ISO 14801. The results demonstrate higher fatigue strength than the predicate Branemark Novum (K000018).

Summary of Non-Clinical Testing:

Since the subject device does not represent a new worst case, data from the predicate device was leveraged in the following aspects of the 510(k).

- Sterile Device Information
 - The sterilization method for the subject devices provided sterile is the same as the predicate. The sterilization method is Gamma radiation and has been validated in accordance with ANSI/AAMI/ISO 11137. Therefore, no additional testing was required.
 - The sterilization methods for the subject devices provided non-sterile and to be end user sterilized are pre-vacuum and gravity moist heat sterilization and have been validated in accordance with ANSI/AAMI/ISO ISO 17665-1.
- Device Packaging
 - The packaging for the subject device is the same as the predicate. This is a titanium cylinder placed in a plastic vial with PVC shrink-wrap and tamper resistant strip. Therefore, no additional testing was required.
- Shelf Life
 - The packaging for the subject device is the same as the predicate and is labeled with a 5 year expiration date. Real time aging was used to determine the expiration dating. Therefore, no additional testing was required.
- Biocompatibility
 - The subject device is manufactured from the same material using the same manufacturing method as the predicate, has the same intended use, and the same patient contact type and duration. Therefore, no additional testing was required
- Surface Treatment
 - The Trefoil implants have the same surface treatment (TiUnite) as the predicate NobelActive implants. The TiUnite surface treatment was qualified through Auger analysis, IR spectrum analysis, and cytotoxicity testing. Therefore, no additional testing was required.

VIII. CONCLUSIONS

The information provided in this submission demonstrates that the device is substantially equivalent to the predicate devices.