DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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Nobel Biocare AB
Charlemagne Chua
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October 20, 2017

Re: K172352
Trade/Device Name: TREFOIL System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 2, 2017
Received: August 3, 2017

Dear Charlemagne 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 (DICE) 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 (DICE) 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,

Mary S. Runner -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

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)*
K172352

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 for 11.5 mm implant and 14.5 mm for 13.0 implant 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)*

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A.4. 510(k) Summary

I. SUBMITTER

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Submitted by
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Date Prepared: October 19, 2017

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

III. PREDICATE DEVICE

Primary predicate:
Nobel Biocare – TREFOIL System (K152836)
This predicate has not been subject to a design-related recall.

Reference predicate:
Nobel Biocare – TREFOIL System (K170135)
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 Trefoil Implants are made of CP4 titanium. The implants are parallel walled and have an internal conical abutment connection. The implants have a 13.0 mm threaded portion and are available with both a 4.5 and 6.0 mm collar height. The apex of the implants have cutting

chambers allowing for self-tapping. The implant bone interface has the TiUnite implant surface treatment.

V. INDICATIONS FOR USE

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 13.0 implant 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

VI. Comparison of Technological Characteristics

Comparison of intended use and indication for use statement

Technological characteristics	Subject Device TREFOIL System	Primary Predicate TREFOIL System (K152836)	Reference Predicate TREFOIL System (K170135)
Intended use	The TREFOIL System is intended for the intraoral treatment of totally edentulous mandibles by providing anchorage of the framework in order to restore chewing function and esthetics. By the aid of the surgical components (guides and templates etc.) three implants are placed in predetermined positions, corresponding to the pre-fabricated prosthetic Framework that is used.	The TREFOIL System is intended for the intraoral treatment of totally edentulous mandibles by providing anchorage of the framework in order to restore chewing function and esthetics. By the aid of the surgical components (guides and templates etc.) three implants are placed in predetermined positions, corresponding to the pre-fabricated prosthetic Framework that is used.	The TREFOIL System is intended for the intraoral treatment of totally edentulous mandibles by providing anchorage of the framework in order to restore chewing function and esthetics. By the aid of the surgical components (guides and templates etc.) three implants are placed in predetermined positions, corresponding to the pre-fabricated prosthetic Framework that is used.
Indication for use statement	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 for 11.5 mm implant and 14.5 mm for 13.0 implant 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	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	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 prerequisites must be fulfilled: - Adequate quantity of bone (minimum width of 7mm; and minimum heights of 13mm for 11.5 mm implant and 14.5mm for 13.0 mm implant). - Adequate mouth opening (minimum 40 mm) to accommodate the guided surgery instruments. - Implant-supported prosthetics seated directly on dedicated implants.

Comparison of Intended use/Indications for Use: The intended use of the TREFOIL System is the same as the primary predicate TREFOIL System. The indications for use of the subject device is the same as the primary predicate with the one change. The first bullet in the prerequisite list of the Indications for use statement has been modified to reflect the change in implant length and is the same as the reference predicate.

Comparison of Implant Technological Characteristics

Technological characteristics		Subject Device	Primary Predicate	Reference Predicate
		TREFOIL System	TREFOIL System (K152836)	TREFOIL System (K170135)
Implant Design Features	Implant Body Design	Parallel walled	Parallel walled	Parallel walled
	Implant Tip Design	Tapered self cutting	Tapered self cutting	Tapered self cutting
	Implant Thread Length	13 mm	11.5 mm	11.5, 13.0 mm
	Implant Diameter	4.93 mm	4.93 mm	4.3, 5.0, 5.5 mm
	Collar Diameter	4.5 mm	4.5 mm	4.5 mm
	Collar Height	4.5, 6.0 mm	4.5, 6.0 mm	4.5 mm
	Connection Type	Morse taper with Internal Hex	Morse taper with Internal Hex	Morse taper with Internal Hex
	Device Material	CP titanium	CP titanium	CP titanium
	Surface modification	TiUnite (anodic oxidation)	TiUnite (anodic oxidation)	TiUnite (anodic oxidation)

Analysis of Differences Between Subject Device and Predicate

Indications for use
The indications for use of the subject device is the same as the primary predicate with the one change. The first bullet in the prerequisite list of the Indications for use statement has been modified to reflect the change in implant length and is the same as the reference predicate.

Technological characteristics
The subject TREFOIL System is an extension of the primary predicate TREFOIL System (K152836) implant length from 11.5 mm to 13.0 mm. All other technological characteristics are the same. The 13.0 mm length is the same as the reference predicate TREFOIL System (K170135)

Summary:

- The only design difference between the subject and primary predicate is the implant length. This length is the same as the reference predicate.
- There is a trade name change to implant name (per K152836). Implant Conical Connect RP used with TREFOIL System will be called Trefoil Implants CC RP.

VII. PERFORMANCE DATA

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 device is the same as the primary predicate (K152836). The sterilization method is Gamma radiation and has been validated in accordance with ANSI/AAMI/ISO 11137. Therefore, no additional testing was required.
- Device Packaging
  - The packaging for the subject device is the same as the primary predicate (K152836). This is a plastic vial with PVC shrink-wrap cap. Therefore, no additional testing was required.
- Shelf Life
  - The packaging for the subject device is the same as the primary predicate (K152836) 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 as the primary predicate (K152836), uses the same manufacturing method as the primary predicate, has the same intended use, and the same patient contact type and duration as the primary predicate. Therefore, no additional testing was required.

- Fatigue Testing
  - The subject device differs from the predicate (K152836) in length only and fatigue testing has been included in K152836. No modification has been made to the implant/abutment connection and no new worst scenario identified. Therefore, no additional fatigue testing was required.

No clinical data was used to support the decision of safety and effectiveness.

VIII. CONCLUSIONS

The TREFOIL System was evaluated for substantial equivalence. In cases where the TREFOIL System could be shown to not represent a worst-case with respect to the predicates, data from these predicate devices was leveraged to support the subject device. Based on technological characteristics, the TREFOIL System was shown to be substantially equivalent to the TREFOIL System (K152836).