DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 11, 2017

Nobel Biocare AB
% Charlemagne Chua
Senior Regulatory Affairs Manager
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K170135
Trade/Device Name: TREFOIL System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA, DZI
Dated: April 5, 2017
Received: April 6, 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 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,

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

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)*
K170135

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 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.

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: April 5, 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
Other Product Code(s): NHA, DZI

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 – NobelSpeedy Implants (K050406)
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 three

diameters 4.3, 5.0, and 5.5 mm. All three diameters are available in lengths of 11.5 and 13mm and have a 4.5 mm tissue collar that has a smooth machined surface without threads. The apex of the implants has cutting chambers 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 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.

VI. Comparison of Technological Characteristics

Comparison of intended use and indication for use statement

Technological characteristics	Subject Device	Primary Predicate
	TREFOIL System	TREFOIL System (K152836)
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.
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 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.	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
Comparison of Intended use/Indications for Use: The intended use of the updated TREFOIL System is the same as the predicate TREFOIL System. The first bullet in the prerequisite list of the Indications for use statement has been modified to reflect the change in implant body design. This change is within the dimensions listed on the predicate indication for use. Additionally, a change in the indications for use was added to ensure 1.5mm of structural support below the implants for the 13.0 mm implants. The indication for use has also been changed to increase the amount of implants reaching primary stability needed for immediate function from 2 to 3. This change is also within the current predicate range and reduces the possibility of implant mobility.		

Comparison of Implant Technological Characteristics

Technological characteristics		Subject Device	Primary Predicate	Reference Predicate
		TREFOIL System	TREFOIL System (K152836)	NobelSpeedy Implants (K050406)
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 Length	16.0 mm overall (11.5 mm body w/ 4.5 mm collar) 17.5 mm overall (13.0 mm body w/ 4.5 mm collar)	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)	7, 8.5, 10, 11.5, 13.0, 15.0, 18.0 mm
	Implant Diameter	4.3, 5.0, 5.5 mm	4.93 mm	4.0, 5.0, 6.0 mm
	Collar Diameter	4.5 mm	4.5 mm	4.1, 5.1, 5.8 mm
	Collar Height	4.5 mm	4.5, 6.0 mm	N/A
	Connection Type	Morse taper with Internal Hex	Morse taper with Internal Hex	External hex Internal Tri-Lobe
	Device Material	CP titanium	CP titanium	CP titanium
	Surface modification	TiUnite (anodic oxidation)	TiUnite (anodic oxidation)	TiUnite (anodic oxidation)

Comparison of Framework Bar Technological Characteristics

Technological characteristics		Subject Device	Primary Predicate
		TREFOIL System	TREFOIL System (K152836)
Bar Design Features	Bar Design	Preshaped single piece design screw retained to implant.	Preshaped single piece design screw retained to implant.
	Intended platform	TREFOIL implant (intenal conical connection)	TREFOIL implant (intenal conical connection with snap fit)
	Materials	Titanium vanadium alloy	Titanium vanadium alloy
	Surface modification	Machined titanium	Machined titanium
	Compensation mechanism	Round abutment and corresponding framework and screw disks	Round abutment and corresponding framework and screw disks
	Prosthetic media	Acrylic	Acrylic
	Fixed cantilever length	18.8 mm	18.8 mm

Comparison of Surgical Tooling Technological Characteristics

Technological characteristics			Subject Device	Primary Predicate
			TREFOIL System	TREFOIL System (K152836)
Surgical tooling type	Drill	Diameter	2.0, 2.4/2.8, 3.2/3.6, 3.8/4.2, 4.2/4.6, 4.2/5.0 mm	2.0, 3.0, 3.8, 4.0, 4.2, 4.4 mm
		Material	Stainless Steel DLC coated	Stainless Steel DLC coated
		Connection	ISO 1797 Type 1	ISO 1797 Type 1
		Markings	All drills marked for 11.5 mm and 13.5 mm length implants	All drills marked for 11.5 mm and 13.5 mm length implants
		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.
		Diameter	4.3, 5.0, 5.5 mm	5.0 mm
		Materials	Stainless Steel DLC coated	Stainless Steel DLC coated
		Connection	ISO 1797 Type 1	ISO 1797 Type 1
		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
		Length	14.0 mm (to stop) 19.7 mm (overall)	14.0 mm (to stop) 19.3 mm (overall)
		Materials	Stainless Steel	Stainless Steel
		Intended use	The stabilizing screw is used to temporarily connect the V-template to the alveolar ridge	The stabilizing screw is used to temporarily connect the V-template to the alveolar ridge

Analysis of Differences Between Subject Device and Predicate

Indications for use
The first bullet in the prerequisite list has been modified to reflect the change in implant body design. This change is within the dimensions listed on the predicate indication for use. Additionally, a change in the indications for use was added to ensure 1.5mm of structural support below the implants for the 13.0 mm implants. The indication has also been changed to increase the amount of implants reaching primary stability needed for immediate function from 2 to 3. This change is also within the current predicate range and reduces the possibility of implant mobility.

Implant technological characteristics
The subject Trefoil implant is a hybrid between the existing Trefoil implant (K152836) and the NobelSpeedy implant (K050406). The subject Trefoil implant has the basic collar and abutment connection as the existing Trefoil implant (K152836) and body design characteristics of the NobelSpeedy implant (K050406). The subject Trefoil implant now has one collar length and two implant body lengths. This maintains the same overall implant lengths as the predicate Trefoil implant (K152836). The available subject Trefoil implant body diameters are different from but within the range of the NobelSpeedy implant (K050406). The subject Trefoil implant was tested using a modified ISO 14801 test protocol and the results favorably compared to the Trefoil implant (K152836).

Framework technological characteristics
The subject TREFOIL System uses the same framework components as the TREFOIL System (K152836) with one exception. The framework no longer has a snap fit. This was done by modifying the round abutment. The subject Trefoil implant and Framework was tested using a modified ISO 14801 test protocol and the results favorably compared to the Trefoil implant (K152836).

Surgical Tooling
The drill for the subject TREFOIL System uses the same materials and basic design but have been modified to accommodate the new Trefoil Implant body profile.

Summary:
The design differences between subject and predicate were evaluated using comparative testing. Differences in technology were evaluated through comparative performance testing.

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 Trefoil Implants, drills, and screw taps 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.
- Device Packaging
    - The packaging for the subject device is the same as the predicate. This is either a plastic vial with PVC shrink-wrap cap (Trefoil Implants) or a thermoform tray with peel top lid (Trefoil drills and screw taps). Therefore, no additional testing was required.

- Shelf Life
    - The packaging for the subject device is the same as the predicate and is labeled with either a 5 year expiration date (Trefoil Implants) or a 3 year expiration (Trefoil drills and screw taps). Real time aging was used to determine the expiration dating. Therefore, no additional testing was required.
- Biocompatibility
    - The Trefoil Implants, drills, screw taps, are manufactured from the same material as the predicate, uses 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.

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 significantly higher fatigue strength than the predicate TREFOIL System (K152836).

Biocompatibility testing for the TREFOIL framework assembly and Stabilizing Screw V-Template was performed in accordance with CEN EN ISO 10993-5, CEN EN ISO 10993-12, and CEN EN ISO 10993-18.

No clinical data was used to support the decision of substantial equivalence.

VIII. CONCLUSIONS

The TREFOIL System was evaluated for substantial equivalence using standard and/or comparative testing. 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 and non-clinical test data included in this submission, the TREFOIL System shown to be substantially equivalent to the TREFOIL System (K152836).