DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 2, 2016

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

Re: K160119
Trade/Device Name: NobelSpeedy® Groovy
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 26, 2016
Received: April 27, 2016

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 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)*
K160119

Device Name
NobelSpeedy Groovy

Indications for Use *(Describe)*

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 bi-cortical 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 restorations 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)

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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1. 510(k) Summary

I. Submitter

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 x7830
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Submitted for:
Nobel Biocare AB
Vastra Hamngatan 1
Goteborg, SE-411 17
Sweden

Date Prepared: June 1, 2016

II. Device

Name of Device: NobelSpeedy® Groovy
Common or Usual Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implants (21 CFR 872.3640)
Regulatory Class: II
Product Code: DZE

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate

- NobelSpeedy® Implants, K050406, Nobel Biocare

Additional Predicate

- Osseotite Certain Dental Implants, K063341, Implant Innovations Inc (3i)

The following is used as reference device within the submission:

- NobelActive Wide Platform (WP), K133731, Nobel Biocare

IV. Device Description

NobelSpeedy® Groovy implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients. They are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The NobelSpeedy® Groovy implants (20 mm, 22 mm, and 25 mm) share the same design characteristics as the existing NobelSpeedy® implants but are longer than the existing range of NobelSpeedy® implants. All NobelSpeedy® implants are made of commercial pure titanium.

V. Intended Use

NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications.

NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

VI. Indications for Use

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 bi-cortical 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 restorations in splinted applications that utilize at least two implants.

Discussion

The Indications for Use statement between the subject and predicate devices are not identical; however, the differences do not alter the intended therapeutic use of the device based on the provided clinical data. Both the subject and predicate devices are intended to restore patient esthetics and chewing function.

VII. Comparison of Technological Characteristics

The subject and primary predicate devices share the following characteristics:

- Single lead thread design
- Tapered apex with bone cutting flutes
- External hex connection
- Materials of construction and implant surface

The subject devices are technologically different from the predicate devices as follows:

- Implant lengths of 22, and 25 mm exceed the lengths of the cited predicate devices

A comparison of the subject and predicate devices is provided in the table below.

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		SUBJECT	PRIMARY PREDICATE	PREDICATE
		NobelSpeedy® Groovy	NobelSpeedy Implants (K050406)	Osseotite Certain Dental Implant (K063341)
Features	Thread Design	Single lead thread with groove	Single lead thread with groove	Single lead thread with groove
	Implant Body Design	Tapered apex with bone cutting flutes	Tapered apex with bone cutting flutes	Tapered and parallel wall
	Implant Length	**20, 22, 25 mm**	7, 8.5, 10, 11.5, 13, 15, 18 mm	7 to 20 mm
	Implant Width	4.0 mm	3.5, 4.0, 5.0, 6.0 mm	3.25, 3.75, 4.0, 5.0 , 6.0 mm
	Connection Type	External Hex	External Hex	Internal Hex
	Device Material	CP Titanium	CP Titanium	CP Titanium
	Surface	TiUnite	TiUnite	Acid-etched
Indications for Use Statement		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 bi-cortical anchorage	NobelSpeedy 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 implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. NobelSpeedy implants may be placed immediately and put into immediate function providing that initial stability requirements detailed in the surgical manual are satisfied. NobelSpeedy implants are indicated for use in soft bone or whenever immediate or early loading is applied. The NobelSpeedy implants incorporate a groove on the	3i dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. In addition, when a minimum of 4 implants, $\geq$ 10 mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.

	SUBJECT	PRIMARY PREDICATE	PREDICATE
	NobelSpeedy® Groovy	NobelSpeedy Implants (K050406)	Osseotite Certain Dental Implant (K063341)
	in cases of reduced bone density NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.	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-groove implants. In addition, the NobelSpeedy implants are preferred in these soft bone indications because bone formation on the TiUnite® 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 implants may be tilted up to 45^{o}. When used with angulations between 30^{o} and 45^{o} a minimum of 4 implants must be used and splinted.	

Discussion

As seen above, the only difference between the subject and predicate devices is the additional of extended implant lengths of 22 and 25 mm.

VIII. Performance Data

The following performance data were provided or relied upon in support of the substantial equivalence determination.

Sterilization
Validation of the gamma irradiation process was previously conducted for the predicate device. There has been no change to the manufacturing or sterilization processes since then; therefore, additional validation is not required.

Shelf-Life
Real-time and accelerated aging studies were conducted in accordance with ISO 11607-1 and 1SO 11607-2 and support that the product remains sterile throughout the duration of the labeled expiry.

Biocompatibility Testing
Biocompatibility testing on the NobelSpeedy® Groovy implants was previously conducted. As the material of construction and manufacturing processes are the same as the predicate device, no additional testing is required to support the biological safety of the subject devices.

Magnetic Resonance (MR) Testing
MR testing sufficient to ensure the safety of the patient was conducted to satisfy the requirements described in the "FDA Guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" and ASTM F2052, ASTM F2119, ASTM F2182, ASTM F2213, ASTM F2503, and IEC 60601-2-33.

Biomechanical Testing
A comparative torque study was conducted on the subject devices in accordance with ISO 13498:2011. The purpose of the study was to evaluate insertion and removal torque during implant placement and removal as well as the yield and maximum torque of the implants.

Clinical Data

Two studies with data of up to several years follow-up was referenced in the submission and support the substantial equivalence of the subject device.

The NobelSpeedy® Groovy implants with the lengths of 20 mm, 22 mm and 25 mm have been used in two investigator-initiated studies for which results have been published. The implants

were placed mainly in the maxilla and one implant was utilized in the mandible. The implants were used in demanding situations such as soft bone and were subjected to immediate loading protocols. The follow-up ranges between 6 months and 57 months for individual implants. All implants were successful and marginal bone remodeling (baseline at implant insertion) as well as soft tissue were in the usual range. These studies are further summarized below:

- Agliardi et al. (Partial Fixed Rehabilitation, *The Journal of Craniofacial Surgery* (2014), Volume 25, Number 3) conducted a prospective, single arm study in which 10 humans with a partially edentulous maxilla were treated. The patients received two NobelSpeedy groovy implants of lengths (one axial and one tilted) of up to 25 mm, whereof the distal implants were tilted. Surgeries included typically the sinus and implants were immediately loaded with fixed bridges. Follow up was 42-57 months (mean 50 months). The survival rate was 100% with stable marginal bone levels and favorable soft tissue results. No biological and mechanical complications occurred.
- Malo et al. (Preliminary Report on the Outcome of Tilted Implant with Longer Lengths (20-25 mm) in Low Density Bone: One-Year Follow-Up of a Prospective Cohort Study, *Clinical Implant Dentistry and Related Research Journal* (2013), Volume 17, Supplement 1) report on a prospective single arm study. A total of 16 humans with fully edentulous arches and low bone density were included and received immediately loaded NobelSpeedy® Groovy implants according the All-on-4 treatment concept. Of the implants used, 43 implants were up to 18 mm in lengths and 16 implants were 20 mm long, 7 implants were 22 mm and 2 implants were 25 mm in length. Patients were followed for 6-26 months (mean 14 months). Survival rate was 100 % and bone level change was -0.85 ($\pm$ 0.45) mm at 1 year, being in the usual range. One mechanical complication (i.e. abutment loosening) occurred that could be fixed.

IX. Conclusion

Although differences in implant length exist between the subject and predicate devices, the testing supports that the subject device is substantially equivalent to the predicate devices.