

APR 04 2014

1.4 510(k) Summary

Submitted by: Phuong Nguyen
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Submitted for: Nobel Biocare AB
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Date of Submission: November 1, 2013

Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3630)
Pro Code: NHA

Trade or Proprietary
or Model Name: NobelProcera Angulated Screw Channel Abutment Replace

Legally Marketed Devices: Nobel Biocare – Esthetic Zirconia Abutment (K031719)

Device Description:

Nobel Biocare's NobelProcera Angulated Screw Channel Abutment Replace is an endosseous dental implant abutment. The abutment attaches directly to Nobel Biocare dental implants with a conical connection and provides a platform for restoration.

Nobel Biocare's NobelProcera Angulated Screw Channel Abutment Replace is designed and made individually to fit the individual requirements for each patient. The abutments are a two piece design with an adapter portion made of titanium vanadium alloy and an abutment portion made of zirconium oxide. The screw channel can be angulated between 0° and 25° as required.

Indications for Use:

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

Summary of testing to demonstrate safety and effectiveness

Non-clinical test data was used to support the decision of safety and effectiveness. Clinical testing was not necessary. Non-clinical testing consisted of performance of fatigue testing in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

Comparison of Technological Characteristics

ATTRIBUTE	CANDIDATE	PREDICATE
	NobelProcera Angulated Screw Channel Abutment Replace	Esthetic Zirconia Abutment (K031719)
Design/ construction	Patient specific / machined	Patient specific / machined
Anatomical Site	Oral Cavity	Oral Cavity
Platform compatibility	Nobel Biocare - Replace	Nobel Biocare - Branemark - Replace
Screw Channel	Variable 0° to 25°	Fixed 0°
Device Material	Implant Adapter - Titanium/vanadium alloy Abutment Body - Zirconium oxide	Zirconium oxide
Indications for Use	The NobelProcera Angulated Screw Channel Abutment Replace are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.	Nobel Biocare's Esthetic Zirconia Abutment is indicated for the treatment of partially edentulous patients requiring prosthetic devices and/or endosseous implants to restore chewing function.

Conclusion

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



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

April 4, 2014

Nobel Biocare AB
C/O Phuong Nguyen
Senior Regulatory Affairs Manager
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K133377

Trade/Device Name: NobelProcera Angulated Screw Channel Abutment Replace
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 25, 2014
Received: March 5, 2014

Dear Ms. Nguyen:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,


Mary S. Runner -S

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

Enclosure

A.3.

Indications for Use

510(k) Number (if known): K133377

Device Name: NobelProcera Angulated Screw Channel Abutment Replace

Indications For Use:

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S

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Page 1 of 1