K102436

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Herbert Crane Director, Global Regulatory Affairs DEC - 9 2010
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Date of Submission:	August 25, 2010
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640) Endosseous Dental Implant Abutment (21 CFR 872.3630)
Trade or Proprietary or Model Name:	NobelActive 3.0
Legally Marketed Device(s):	NobelActive Internal Connection Implant (K071370)

Device Description:
Nobel Biocare's NobelActive 3.0 is an endosseous dental implant and abutment system. The implant is 3.0 mm diameter and available in lengths from 10.0 mm to 15 mm. Implants are made from CP titanium. Healing, temporary, and final abutments are included in the system. Abutments are made from titanium vanadium alloy.

Indications for Use:
The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

Non-Clinical Testing:
Non-clinical test data was used to support the decision of safety and effectiveness. 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. The testing indicates that the device is strong enough to withstand the anticipated forces.

Clinical Testing:
Non-clinical test data was used to support the decision of safety and effectiveness.

Conclusions:
The testing indicates that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

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Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE
	NobelActive 3.0	NobelActive Internal Connection Implant (K071370)
Trade Name	NobelActive	NobelActive
Anatomical Site	Oral Cavity	Oral Cavity
Implant Material	Titanium	Titanium
Implant Diameters	3.0 mm	3.5, 4.3, 5.0 mm
Implant Lengths	10.0, 11.5, 13.0, 15.0 mm	10.0, 11.5, 13.0, 15.0 mm
Abutment Material	Titanium Vanadium Alloy	Titanium Vanadium Alloy
Abutment angulation	0, 15 deg	0, 15 deg
Implant/Abutment Connection	Internal Hex	Internal Hex
Indications for Use	The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.	Nobel Biocare's NobelActive implants are endosseous implant 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 NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Herbert Crane
Director, Global Regulatory Affairs
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

FEB - 7 2011

Re: K102436
Trade/Device Name: NobelActive 3.0
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 16, 2010
Received: November 17, 2010

Dear Mr. Crane:

This letter corrects our substantially equivalent letter of December 9, 2010.

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 (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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

1.3 Indications for Use

DEC - 9 2010

510(k) Number (if known): K102436

Device Name: **NobelActive 3.0**

Indications For Use:

The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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