

1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Kam Leung, Ph.D., RAC
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Date of Submission: September 10, 2007

Classification Name: Endosseous dental implant abutment (21 CFR 872.3630)

**Trade or Proprietary
or Model Name:** NobelActive Multi Unit Abutment

Legally Marketed Device(s): SFB & CFB Angled Abutments (K062749)
SFB and CFB Implant System (K061003)

Device Description:

NobelActive Multi Unit Abutments are artificial tooth abutments designed to fit and function on the NobelActive Implants. It is an internal hexagonal design similar to the previous SFB (renamed NobelActive) Abutments. The material of construction is the same as the previous SFB Abutments. The NobelActive Multi Unit Abutments differ from the predicate device in trade name and design.

Indications for Use:

NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 2007

Nobel Biocare AB
C/O Mr. Herbert Crane
Director, Global Regulatory Affairs
Nobel Biocare, USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K072570
Trade/Device Name: NobelActive Multi Unit Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: NHA
Product Code: II
Dated: December 5, 2007
Received: December 6, 2007

Dear Mr. Crane:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

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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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072570

Device Name: NobelActive Multi Unit Abutment

Indication For Use:

NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Prescription Use
 (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
 (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shelley A. Murphy
 (Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072570

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