Zimmer Dental
1900 Aston Avenue
Carlsbad, CA 92008
760.929.4300 (ph)
760.431.7811 (fax)

Traditional 510(k)
PRE-MARKET NOTIFICATION 510(k)

JAN 23 2006

510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave.
	Carlsbad, CA 92008
Phone:	760-929-4300
Contact:	Erin L. McVey
Date Prepared:	January 5, 2006

2. Device Name: Zimmer® One-Piece Implant System

   Device Classification Name: Endosseous Dental Implant

3. Predicate Device(s):

   Zimmer Dental Inc., Screw-Vent® MTX™ Selective Surface Implant (Cat. No. SVMB13)/ Zimmer Dental Hex-Lock™ Abutment (Cat. No. HLA3/3)

   Nobel Biocare Inc., NobelDirect™ 3.0 (Cat. No. 31456)

4. Device Description:

   The Zimmer® Dental One-Piece Implant is a one-piece endosseous dental implant which is a combination of implant and abutment sections. The implant is composed of titanium alloy. The abutment portion is pre-prepared and contoured for esthetic restoration. The abutment portion of the implant features a pre-prepared margin to facilitate the restoration process. The implant section is designed for ease of implantation and with greater surface area for osseointegration. The implant section surface is treated to facilitate osseointegration. In addition, the implant section is tapered with either double or triple-lead threads, depending upon the apical diameter.

5. Intended Use:

Zimmer® One-Piece 3.7mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. Zimmer® One-Piece 3.7mm implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. The Zimmer® 3.7mm One-Piece implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

Zimmer® One-Piece 3.0mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The Zimmer® One-Piece 3.0mm implant must be splinted if two or more are used adjacent to each other. The Zimmer® One-Piece 3.0mm implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

6. Device Comparison:

The Zimmer® One-Piece implant is substantially equivalent to NobelDirect™ 3.0, as evidenced in mechanical testing. The Zimmer® One-Piece implant differs from the NobelDirect™ 3.0 implant with regard to certain features such as, pre-prepared, contoured abutment section, and implant thread pattern and shape. The Zimmer® One-Piece implant is substantially equivalent to the NobelDirect™3.0 implant in that it is manufactured from one piece of titanium with the abutment and implant portions combined. It is equivalent to the two-piece Zimmer Dental Screw-Vent®/Hex-Lock™ Abutment assembly in that it is manufactured from the same titanium alloy and has similar implant section design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2006

Mr. Erin L. Mcvey
Regulatory Affairs Specialist
Zimmer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008

Re: K052997
Trade/Device Name: Zimmer® One-Piece Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: January 5, 2006
Received: January 6, 2006

Dear Mr. Mcvey:

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.

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. Ao, 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

Indications for Use

510(k) Number (if known): K052997

Device Name: **Zimmer® One-Piece Implant**

Indications For Use:

Zimmer® One-Piece 3.7mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. Zimmer® One-Piece 3.7mm implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. The Zimmer® 3.7mm One-Piece implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

Zimmer® One-Piece 3.0mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The Zimmer® One-Piece 3.0mm implant must be splinted if two or more are used adjacent to each other. The Zimmer® One-Piece 3.0mm implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K052997