



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 30 2004

Ms. Jeff Rassoli  
President  
DíamoDent™  
2737 East Regal Park Avenue  
Anaheim, California 92806

Re: K034022  
Trade/Device Name: UCLA and Cement-On Abutments and Accessories  
Regulation Number: 872.3640  
Regulation Name: Endosseous Implant  
Regulatory Class: III  
Product Code: DZE  
Dated: December 16, 2003  
Received: December 29, 2003

Dear Mr. Rassoli:

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 (301) 594-4613. 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/dsma/dsmamain.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): K034022

Device Name: UCLA and Cement-On Abutments

### Indications for Use:

The UCLA Abutments and Cement-On Abutments are designed for use with commercially available dental implant systems. These abutments are straight abutments and are NOT angled abutments. The abutments will seat directly on implants and are sub-structure of prosthesis. Some abutments are used as pattern in dental laboratory to make prosthesis, such as UCLA Plastic Cylinders.

All abutments have been designed specifically to be compatible and to be used with each of the following implant systems and sizes (for engineering drawings please refer to Attachment GG).

<u>IMPLANT COMPANIES</u>	<u>IMPLANT SYSTEMS</u>	<u>IMPLANT SIZE (mm)</u>
Nobel Biocare	NobelPerfect	3.5, 4.3 & 5.0mm
	Replace Select	3.5, 4.3, 5.0 & 6.0mm
Straumann	ITI	3.5mm Shoulder Diameter Narrow Neck Solid Screw
	ITI	4.8mm Shoulder Diameter Solid Screw
	ITI	6.5mm Shoulder Diameter Wide Neck Solid Screw
Dentsply/ Friadent	Frialit-2	3.4, 3.8, 4.5, 5.5 & 6.5mm
	XiVE	3.4, 3.8, 4.5 & 5.5mm
3i	Osscotite Certain	4.0, 5.0 & 6.0mm

Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

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)

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

510(k) Number: K034022

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