DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

Mr. Jeff Rassoli
President
Diamodent
2737 East Regal Park Avenue
Anaheim, California 92806

Re: K010619
Trade/Device Name: UCLA and Universal Abutments
Regulation Number: 872.3640
Regulation Name: Wide Diameter Abutments or Wide Platform Abutments
Regulatory Class: III
Product Code: DZE
Dated: June 29, 2001
Received: July 3, 2001

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.

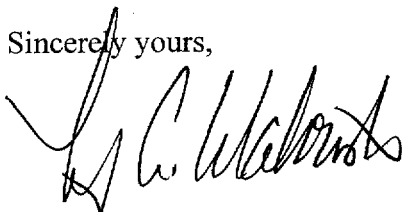
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Re: K010619

Device Name: Wide and Regular Diameter Abutments and Hader Bar

Indications for Use:

Wide and Regular diameter 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 Cylinder.

Hader bar is used to attach two or more abutments together for removable denture cases.

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 see attachment GG).

IMPLANT COMPANIES	IMPLANT SYSTEMS	IMPLANT SIZE (mm)	
Nobel Biocare	Wide Platform (WP) Branemark	5mm	
3i	Wide Diameter	5mm	
3i	Wide Diameter	6mm	
Steri-Oss	HL Threaded	3.25mm	
Steri-Oss	Replace	3.5mm	
Steri-Oss	Replace	4.3mm	
Steri-Oss	HL Threaded & Replace	5mm	
Steri-Oss	HL Threaded & Replace	6mm	
Paragon	Screw-Vent	3.3 and 3.7mm	3.5mmD Platform
Paragon	Screw-Vent	4.7mm	4.5mmD Platform
Paragon	Screw-Vent	6mm	5.7mmD Platform

Hader Bar in Titanium, Plastic and Gold materials

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010660