DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 28 2000

Mr. Jeff Rassoli
President
DiamoDent, Inc.
695 South Morningstar Drive
Anaheim, California 92808

Re: K993129
Trade Name: UCLA/Universal Abutments
Regulatory Class: III
Product Code: DZE
Dated: December 21, 1999
Received: December 28, 1999

Dear Mr. Rassoli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4690. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Patricia Cucinotta for

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

Enclosure

K993129

Device Name: UCLA/Universal Abutments, Impression Posts, Implant Analogs, Cement Retained Abutments, Temporary Abutments, Tools, and Accessories.

Indications for Use:

- Universal and UCLA Abutments are used as patterns for casting of prostheses. The prosthesis (restoration) will be fastened directly to implant by using a screw.
- Impression Posts are used to register the location and position of the implants in mouth.
- Implant Analogs are replicas of the implants and are mounted in stone model.
- Cement Retained Abutments are used when the abutment is being used as substructure and the crown is attached on it by using dental cement.
- Temporary Abutments are used while the prostheses are being made. This abutment will be used for a short time. A resin material such as Acrylic will be attached to it directly or by cement.
- Tools and Accessories, such as screwdrivers are used to screw in or tighten the screws, coping screw and housing are used to screw retain the coping on the prosthesis. Drill and reamer are used to smooth out the inner surfaces of abutments after casting.

All Universal, UCLA, Cement Retained and Temporary Abutments, Implant Analogs and Impression Posts are compatible and will be used with Brånemark Regular Platform (RP) implants from Nobel Biocare, which have 2.70mm external hexagon and 2mm thread. All abutments will be used for fully or partially edentulous and/or for single tooth dental prostheses.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993129

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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