DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1998

Ms. Gisela N. Everngam
Sales Director
Official Correspondent
European Dental Imports, Incorporated
49 Emerson Road
P.O. Box 799
Durham, New Hampshire 03824-0799

Re: K980661
Trade Name: Cera E Dental Alloy
Regulatory Class: II
Product Code: EJS
Dated: February 12, 1998
Received: February 20, 1998

Dear Ms. Everngam:

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) 594-4692. 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,

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

Enclosure

510(k) Premarket Notification for Cera E Dental Alloy
Submitted by european dental imports, inc., Reg#1218814

INDICATIONS FOR USE:

510(K) Number: _____

Device Name: Cera E Dental Alloy

Indications for Use:

Used by a dental lab technician, under the direction of an attending dentist, to cast elements of fixed and removable dental prostheses:

precious metal inlays, onlays, and crowns;

precious metal bridges, bars, and attachments;

precious metal copings and bridges for porcelain-fused-to-metal restorations.

When used for porcelain-fused-to-metal restorations it is intended by the manufacturer that only Carrara Porcelain products be used with the Cera E alloy.

After fabrication and finishing the completed prosthesis is approved and placed in the patient's mouth by the dentist.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980101

Prescription Use ✓ OR Over the Counter Use____
(Per 21 CFR 801.109)