DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

Mr. Andrew Rowe
QA Manager
American Green Dental Manufacturing, Inc.
3432 East 14th Street
Los Angeles, California 90023

Re: K033045
Trade/Device Names: Dream Bond, DreamCast V, DreamCast Chrome, Dream FlexiCast, and Dream LitheCast
Regulation Number: 21 CFR 872.3710
Regulation Name: Base Metal Alloy
Regulatory Class: II
Product Code: EJH
Dated: December 06, 2003
Received: December 15, 2003

Dear Mr. Rowe:

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.

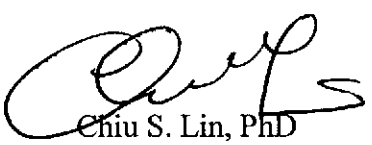
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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. 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 Part 807.97) you may obtain. 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,



Chiu S. Lin, PhD
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) # K033045

Device Name:- General:- Dental Alloys

Device Name:- Specific:- "DREAMBOND""DREAMCAST CHROME" "DREAMCAST V" "DREAM FLEXICAST" "DREAM LITHECAST"

"DREAMBOND" (Ceramic dental casting Alloy) is used in dental laboratories, suitable for fabrication of metal-ceramic dental restorations.

"DREAMCAST CHROME" (Partial Denture Dental Casting Alloy) is for the use in dental laboratories, suitable for preparation of removable dental applications.

"DREAMCAST V" (Ceramic dental casting Alloy) is used in dental laboratories, suitable for fabrication of metal-ceramic dental restorations.

"DREAM FLEXICAST"" (Partial Denture Cobalt Base Alloy") is for the use in dental laboratories, suitable for preparation of removable dental applications.

"DREAM LITHECAST" (Ceramic dental casting Alloy Nickel & Beryllium Free) is used in dental laboratories, suitable for fabrication of metal-ceramic dental restorations.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mully for MCR

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

510(k) Number: K033045