DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

Heraeus Kulzer GmbH & Company KG
C/O Ms. Cheryl V. Zimmerman
Manager, Quality Operations and Compliance
Heraeus Kulzer, Incorporated
4315 South Lafayette Boulevard
South Bend, Indiana 46614

Re: K034049
Trade/Device Names: Herador EC, Herador PF, Herador H, Herador NH, Herador G, Herador GG, Herador MP, Heraloy U, Heraloy G, Herabond N, Albabond C, Albabond B, Albabond A, Bio Heranorm, Mainbond KF, Keramikgold PKF, Hera KF, Alba KF, Maingold SG, Maingold MP, Maingold OG, Bio Maingold TK, Maingold G, Maingold GV, Bio Maingold IT, Bio Maingold I, Hera SG, Hera PF, and Alba SG
Regulation Number: 21 CFR 872.3060
Regulation Name: Gold Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT and EJS
Dated: December 18, 2003
Received: January 08, 2004

Dear Ms. Zimmerman:

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

510(k) Number (if Known): K034049

Device Name:

Herador EC	Mainbond KF
Herador PF	Keramikgold PKF
Herador C	Hera KF
Herador H	Alba KF
Herador NH	Maingold SG
Herador G	Maingold MP
Herador GG	Maingold OG
Herador MP	Bio Maingold TK
Heraloy U	Maingold G
Heraloy G	Maingold GV
Herabond N	Bio Maingold IT
Albabond C	Bio Maingold I
Albabond B	Hera SG
Albabond A	Hera PF
Bio Heranorm	Alba SG

Indications For Use:

Reconstruction of porcelain to metal dental restorations/reconstruction of dental restorations.

(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 K034049

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

(Optional Format 1-2-96)