SEP 2 3 2003

Heraeus

K030903

510(k) Summary

Applicant's name and address	Heraeus Kulzer GmbH & Co. KG Grüner Weg 11 D-63450 Hanau
Contact persons	Dr. K.-D. Kühn phone: +49 6081 959-264 fax: +49 6081 959-288 klaus-dieter.kuehn@heraeus.com Dr. C. Tuchscherer phone: +49 6081 959-278 fax: +49 6081 959-288 christian.tuchscherer@heraeus.com
Date of summary	March 19th, 2003
Device trade name	OSTEOPAL®
Classification name	Bone Cement
Identification of the marketed device Osteopal® to which equivalence is claimed	OSTEOPAL® (or Palacos® E-flow, respectively) PMA (Merck and S.-P.) P810020 1998
Description of the device	Osteopal® is an acrylic bone cement for use in orthopedic surgery. It is formed from powder and liquid by exothermic polymerization. It secures the fixation of the grafted artificial joint improving the transfer of forces at the interface implant - bone.
Intended use	Fixation of prostheses in the bone (partial or total hip joint replacement at the hip, knee or other joints).
Comparison of technological characteristics	This is the known Osteopal® marketed by Merck (as Palacos E-Flow marketed by S.-P., respectively).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2003

Dr. K. D. Kühn
Head of Department
Heraeus Kulzer GmbH & Co. KG
Grüner Weg 11
Hanau,
Germany D-63450

Re: K030903
Trade/Device Name: OSTEOPAL®
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: June 25, 2003
Received: July 14, 2003

Dear Dr. Kühn:

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) 594-4659. 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 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Abbreviated 510(k)

Osteopal®

Heraeus

Intended Use

Osteopal® is intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixatio of polymer or metallic prosthetic implants to living bone.

for

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030903