K050085

Abbreviated 510(k)

Osteopal® V

SEP 14 2005

Heraeus

510(k) Summary

Date of summary	Jan 7th, 2005
Device trade name	**OSTEOPAL® V**
Common Name	PMMA Bone Cement
Classification name	Bone Cement, 888.3027
Identification of the marketed device to which equivalence is claimed	**OSTEOPAL®** K030903 PMA P810020 1998
Description of the device	Osteopal® V is an acrylic cement for use in vertebroplasty and kyphoplasty. It is formed from powder and liquid by exothermic polymerization.
Intended use	OSTEOPAL® V bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.
Comparison of technological characteristics	Osteopal® V contains exactly the same chemical components as Osteopal®. The only difference is the significantly higher content of zirconium dioxide in Osteopal® V for better X-ray contrast, combined with a lower viscosity.
Submitted by	Dr. Christian Tuchscherer phone: +49 6081 959-278 fax: +49 6081 959-252 christian.tuchscherer@heraeus.com Signature 7.9.2005 Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

Dr. Christian Tuchscherer
Heraeus Kulzer GmbH
Division Heraeus Medical
Philipp-Reis-StraBe 8/13
D-61273 Wehrheim / Ts.
Germany

Re: K050085
Trade/Device Name: OSTEOPAL® V
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD, NDN
Dated: August 24, 2005
Received: August 31, 2005

Dear Dr. Tuchscherer:

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 (240) 276-0120 . 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **OSTEOPAL® V**

Indications For Use:

OSTEOPAL® V bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

Prescription Use yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use no (21 CFR 807 Subpart C)

(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 General, Restorative, and Neurological Devices

510(k) Number K050086