

NOV 18 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

K990290

Submitter: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley

Product Code: 84GXP, 84JBA

Device Name: Craniofacial Calcium Phosphate Ceramic Bone Filler

The Craniofacial Calcium Phosphate Ceramic Bone Filler is a self-setting calcium phosphate cement indicated for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects as well as in the augmentation and restoration of bony contour in the craniofacial skeleton.

Craniofacial Calcium Phosphate Ceramic Bone Filler is comprised of a calcium phosphate powder and a liquid component. The two components are mixed to produce a homogenous paste, which can then be applied to burr holes, bone gaps, and other defect sites.

The Craniofacial Calcium Phosphate Ceramic Bone Filler is a biocompatible material, and is similar to the predicate device used in the same non-load bearing indications. Biocompatibility testing and animal studies demonstrate the safety of the material. The material is found to be non-toxic, non-mutagenic, non-hemolytic, and non-pyrogenic. Mechanical testing determined the material has adequate strength for the intended use.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K990290
Craniofacial Calcium Phosphate Ceramic Bone Filler
Regulatory Class: II
Product Code: GXP
Dated: August 26, 1999
Received: August 27, 1999

Dear Ms. McKinley:

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.

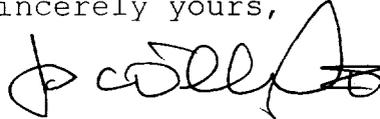
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

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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) 594-4659. 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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K990290

DEVICE NAME: Craniofacial Calcium Phosphate Ceramic Bone Filler

INDICATIONS FOR USE:

The Craniofacial Calcium Phosphate Ceramic Bone Filler is a self-setting calcium phosphate cement intended for the use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

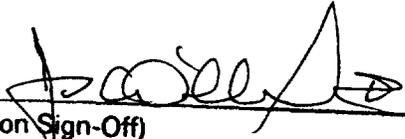
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-
(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990290