K021440

P1/2

AUG 0 2 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:

Bonesource® HAC

General Information

Proprietary Name:	Bonesource® HAC
Common Name:	Hydroxyapatite Cement (HAC)
Proposed Regulatory Class:	Class II
Device Classification:	84GXP 882.5300 Methyl Methacrylate for Cranioplasty 79FWP 878.3550 Prosthesis, Chin, Internal
Submitter:	Stryker Instruments Leibinger Division 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	9610726
Contact Person:	Wade T. Rutkoskie Regulatory Affairs Associate Telephone: 616-323-4226 Fax: 616-323-4215
Summary Preparation Date:	May 3, 2002

Predicate Device

BoneSource® HAC is substantially equivalent to BoneSource® Hydroxyapatite Cement Expanded Kit (K991398), BoneSource® Hydroxyapatite Cement (K953339, K964537, and K970400), Biomet Inc.'s Craniofacial Calcium Phosphate Ceramic Bone Filler (K990290) and Injectable Mimix™ (K012569).

Device Description

The packaging contains the following: BoneSource® powder in a plastic bowl with a foil lid. Sodium phosphate sterile solution in a glass syringe with a plastic cap. A polycarbonate mixing spatula, and an instruction for use card packed in a Polyethylene Terephthalate Glycol Modified (PETG) tray. The kit is terminally sterilized by gamma irradiation. Packages are being provided in sizes ranging from 5g to 50g.

Intended Use

BoneSource® is a self-setting, calcium phosphate cement intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

Substantial Equivalence

BoneSource® HAC is substantially equivalent to BoneSource® Hydroxyapatite Cement (HAC) 510 K's K991398, K953339, K964537, and K970400. And that of the predicate devices Biomet Inc.'s Craniofacial Calcium Phosphate Ceramic Bone Filler (K990290) and Injectable Mimix™ (K012569). The subject device and equivalent products are all classified as Methyl Methacrylate for Cranioplasty, intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton. The BoneSource® HAC raises no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2002

Mr. Wade T. Rutkoskie
Regulatory Affairs Representative
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, MI 49001

Re: Re: K021440
Trade Name: BoneSource HAC®
Regulation Number 882.5300 and 878.3550
Regulatory Name: Methyl Methacrylate for Cranioplasty and Prosthesis, Chin, Internal
Regulatory Class: Class II
Product Code: GXP and FWP
Dated: May 3, 2002
Received: May 6, 2002

Dear Mr. Rutkoskie:

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.

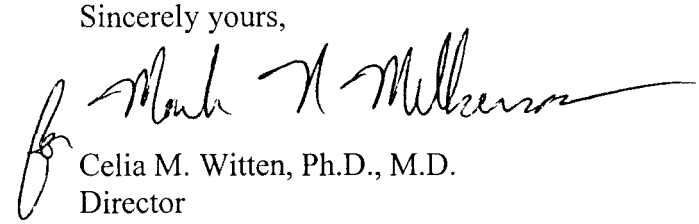
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): _____

Device Name: Bonesource® HAC

Indication For Use:

BoneSource® is a self-setting, calcium phosphate cement intended for use in the repair of neurosurgical burr holes, contiguous 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_____ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

for _____ (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021440