OCT 3 0 2003

K032366
1 of 2

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 Associate Manager RA/QA Telephone: 269-323-4226 Fax: 269-323-4215
Summary Preparation Date:	July 28, 2003

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Equivalent Products

BoneSource® HAC Fast Setting Cement is substantially equivalent to BoneSource® HAC (K021440) and Walter Lorenz QuickSet Mimix™ (K023718). See Appendix 1.

Device Description

The packaging contains the following: BoneSource® powder in a plastic bowl with a foil lid, sodium phosphate sterile solution in a syringe or vial, and a polycarbonate mixing spatula packaged in a Polyethylene Terephthalate Glycol Modified (PETG) tray. The kit is terminally sterilized by gamma irradiation. Kits may be provided in several different sizes.

Indications for Use

BoneSource® HAC Fast Setting Cement 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 Fast Setting Cement is substantially equivalent to BoneSource® HAC K021440 and Walter Lorenz QuickSet Mimix™ K023718. 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. BoneSource® HAC Fast Setting Cement 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

OCT 3 0 2003

Mr. Wade T. Rutkoskie
Associate Manager RA/QA
Stryker Leibinger
4100 E. Milham Avenue
Kalamazoo, MI 49024

Re: K032366
Trade Name: BoneSource™ HAC Fast Setting Cement
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate for Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: July 28, 2003
Received: August 1, 2003

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.

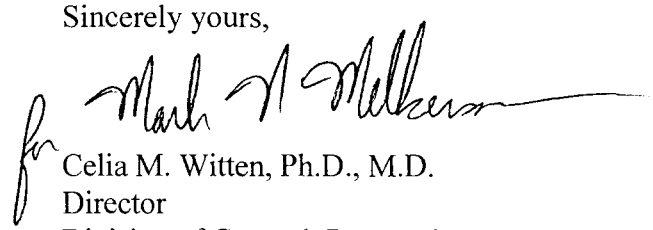
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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,



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

510(k) Number (if known): K032366

Device Name: Bonesource® HAC Fast Setting Cement

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)

(Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032366