FEB - 9 2005

K 043334

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
BoneSource® HAC Rapid Setting Cement

Proprietary Name:	BoneSource® HAC Rapid Setting Cement
Common Name:	Hydroxyapatite Cement
Proposed Regulatory Class:	Class II
Device Classification:	84GXP 882.5300 Methyl Methacrylate for Cranioplasty 79FWP 878.3550 Prosthesis, Chin, Internal
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 269-323-4226
Submitter's Registration #:	1811755
Manufacturer's Registration #:	9610726
Contact Person:	Wade T. Rutkoskie Associate Manager RA QA Phone: 269-323-4226 Fax: 269-323-4215
Summary Preparation Date:	December 1, 2004

Intended Use

BoneSource® HAC Rapid 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. This indication for use is identical to the predicate device.

Substantial Equivalency Information

BoneSource® HAC Rapid Setting Cement is substantially equivalent to BoneSource® HAC (K032366).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2005

Mr. Wade T. Rutkoskie
Manager Regulatory Affairs, Quality Assurance
Stryker Instruments
4100 East Milham Ave.
Kalamazoo, Michigan 49024

Re: K043334
Trade/Device Name: Bone Source® HAC Rapid Setting Cement
Regulation Number: 21 CFR 882.5300, 21 CFR.878.3550
Regulation Name: Methyl methacrylate for cranioplasty, Chin prosthesis
Regulatory Class: II
Product Code: GXP, FWP
Dated: January 24, 2005
Received: January 26, 2005

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 (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 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

Indications for Use

510(k) Number (if known): K

Device Name: BoneSource® HAC Rapid Setting Cement

Indications For Use:

BoneSource® HAC Rapid 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.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

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

510(k) Number K043334