SEP 2 2 1999

K991358

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS:
BONESOURCE® HYDROXYAPATITE CEMENT (HAC) EXPANDED KIT

General Information

Proprietary Name:	BoneSource® Hydroxyapatite Cement (HAC) Expanded Kit
Common Name:	Hydroxyapatite Cement (HAC)
Classification Name(s):	Prosthesis, Chin, Internal Methyl Methacrylate for Cranioplasty
Classification Code(s):	79FWP 87GXP
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	2183449
Contact Person:	Kristyn R. Kelley Project Engineer Quality Assurance and Regulatory Affairs 800-253-7370 x5045
Summary Preparation Date:	April 14, 1999

Predicate Device

The BoneSource® Hydroxyapatite Cement (HAC) Expanded Kit is substantially equivalent to BoneSource Hydroxyapatite Cement (K953339, K864537 and K970400) and to Norian® CRS™ Craniofacial Repair System (K973789).

Device Description

The BoneSource® Hydroxyapatite Cement (HAC) Expanded Kit contains the previously-cleared BoneSource hydroxyapatite cement powder along with a new prefilled syringe containing sodium phosphate solution and a mixing spatula. Kits are being provided in sizes ranging from 5 g to 50 g.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1999

Ms. Kristyn R. Kelley
Project Engineer
Quality Assurance and Regulatory Affairs
Stryker®Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K991398
Trade Name: BoneSource Hydroxyapatite Cement (HAC)
Regulatory Class: II
Product Code: GXP, FWP
Dated: July 19, 1999
Received: July 20, 1999

Dear Ms. Kelley:

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.

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. Furthermore, for questions regarding 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): ~~not known~~ K991398

Device Name: BoneSource® Hydroxyapatite Cement (HAC), Expanded Kit

Indications For Use:

The BoneSource® Hydroxyapatite Cement (HAC) Expanded Kit is indicated for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects with a surface area no larger than $25cm^2$ per defect. BoneSource is also indicated for augmentation or restoration of bony contour in the craniofacial skeleton including the fronto-orbital, malar and mental areas.

(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 Devices
510(k) Number K991398

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The- Counter Use No

(Optional Format 1-2-96)