K 042691

NOV - 8 2005

COOK®

Cook Incorporated
P.O. Box 489
Bloomington, IN 47402-0489
Phone: 800 468-1379
www.cookgroup.com

510(k) SUMMARY

Submitted By:	COOK INCORPORATED 750 Daniels Way, P.O. Box 489 Bloomington, IN 47402-0489
Contact Person:	Earl E. Knight III, MPA Tel: (812) 339-2235 Fax: (812) 332-0281
Date Prepared:	September 28, 2004
Device:	
Trade Name:	Vertefix™ Vertebroplasty Procedure Set
Common/Usual Name	Filler, Bone Cement (For Vertebroplasty)
Proposed Classification:	Polymethylmethacrylate (PMMA) Bone Cement 21 CFR §888.3027, Class II
Product Code/Panel Code:	NDN—Orthopedic

Intended Use:
Vertefix™ Radiopaque Bone Cement is indicated for the fixation of vertebral compression fractures during a vertebroplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Predicate Devices:

Manufacturer	Device Name	510(k) #
Stryker Corp.	Spineplex™ Radiopaque Bone Cement	K032945
Kyphon, Inc.	KyphX® HV-R Bone Cement Model C01A	K041584

Device Description:
The Vertefix™ Vertebroplasty Procedure Set contains the Vertebroplasty Injector Kit and Vertefix™ Radiopaque Bone Cement. The bone cement consists of two separate, pre-measured sterilized components: 20g polymer powder and 9.2g liquid monomer. The powder contains 30% barium sulfate as a radiopacifier.

Substantial Equivalence:
The subject device is similar with respect to intended use, chemical composition, and fundamental scientific technology of commercially available predicate devices in terms of section 510(k) substantial equivalence; any differences that may exist do not significantly affect the safety and effectiveness of the device.

Non-Clinical Test Data:
The results of these tests provide reasonable assurance that Vertefix™ Radiopaque Bone Cement has been designed and tested to assure conformance to the requirements for its use as a bone cement. Testing conducted on the device includes: material and chemical analyses, mechanical testing, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2005

Thalia Brine
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47402-1379

Re: K042691
Trade/Device Name: Vertefix™ Vertebroplasty Procedure Set
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN
Dated: October 4, 2005
Received: October 6, 2005

Dear Ms. Brine:

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 Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K042691

Device Name: Vertefix™ Vertebroplasty Procedure Set

Indications for Use:

Vertefix™ Radiopaque Bone Cement is indicated for the fixation of vertebral compression fractures during a vertebroplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use X OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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, and Neurological Devices

510(k) Number K042691