JUL - 7 2004

K041584

Tab 5

Premarket Notification [510(k)] Summary

Trade Name:	**KyphX® HV-R™ Bone Cement**
Common Name:	Bone Cement
Classification /Name:	Class II Bone Cement: 21 CFR, part 888.3027
Device Code:	NDN
Manufacturer's Name: Address:	Kyphon Inc. 1221 Crossman Avenue Sunnyvale, CA 94089
Corresponding Official: Title: Address: Telephone:	Cindy Domecus Vice President, Clinical Research and Regulatory Affairs 1221 Crossman Avenue Sunnyvale, CA 94089 408-222-6740
Predicate Device(s):	K033801: KyphX® HV-R™, Model C01A K002652: Stryker Howmedica Surgical Simplex®P Radiopaque pre-packed in ACM and MixEvac II. K032945: Stryker Spineplex™ Radiopaque Bone Cement
Intended Use:	KyphX® HV-R™ bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemagioma and giant cell tumor.

Any statement regarding "substantial equivalence" made in this submission only relates to whether the product addressed in this submission may be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in any patent proceeding, including patent infringement litigation or proceeding before any Patent Office. The present submission and statements therein therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in this submission, or its use, may be considered indistinct, from a patentability perspective, from any of the other devices referenced in this filing.

Device Description:

Like the predicate devices, KyphX® HV-R™ Bone Cement is provided as a two-component system. The powder component consists of a PMMA copolymer (polymethyl methacrylate/methyl-methacrylate-styrene-copolymer) with barium sulfate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methylmethacrylate monomer, with the addition of hydroquinone as a stabilizer and N,N-dimethyl-p-toluidine as a promoter. The powder and liquid components are mixed prior to use.

Table 5-1 compares the chemical composition of KyphX® HV-R™ Bone Cement to the Surgical Simplex® P predicate device.

Table 5-1: Chemical Composition of KyphX® HV-R and Surgical Simplex®P

Chemical Composition	KyphX® HV-R™	Surgical Simplex® P
Powder	20 g. packet of sterile powder	20 g (half-dose) packet of sterile powder
Polymethyl methacrylate / methyl methacrylate-styrene copolymer	68.0% w/w	88.5% w/w
Barium sulfate	30.0% w/w	10.0% w/w
Benzoyl peroxide	2.0% w/w	1.5% w/w
Liquid	10 ml vial of sterile liquid	10 ml (half-dose) vial of sterile liquid
Methyl methacrylate (monomer)	99.1% v/v	97.4% v/v
N, N-dimethyl-p-toluidine	0.90% v/v	2.6% v/v
Hydroquinone	75 ppm	75 ± 15 ppm

Mechanical Tests:

KyphX® HV-R™ Bone Cement was tested in direct comparison to the Surgical Simplex® P predicate device and verified substantially equivalent, as defined by ISO 5833:2002, "Implants for Surgery - Acrylic resin cements."

Clinical Discussion:

Clinical information demonstrates that the intended use of KyphX® HV-R™ Bone Cement is substantially equivalent to the Surgical Simplex® P indication for the fixation of pathological fractures, to the KyphX® HV-R™ predicate indication for the treatment of pathological fractures of the vertebral body due to osteoporosis using a kyphoplasty procedure, and to the Spineplex™ bone cement for use in benign and metastatic lesions.

Biocompatibility:

The materials used in KyphX® HV-R™ Bone Cement meet the requirements for "Implant, Tissue/Dentin/Bone, Permanent Contact" described in the FDA Blue Book Memorandum #G95-1. KyphX® HV-R™ Bone Cement was tested in direct comparison to the Surgical Simplex® P predicate device and verified substantially equivalent, as defined by ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."

Sterilization:

The KyphX® HV-R™ Bone Cement is sterile and non-pyrogenic. The solid components and pouch are sterilized with gamma radiation to a Sterility Assurance Level (SAL) of 10^{-6}. The liquid components are sterilized with filtration methods to an SAL of 10^{-3}. The outer packaging containing the liquid component is sterilized with ethylene oxide gas. The bone cement is intended for single use only.

Substantial Equivalence:

The information submitted in this pre-market notification supports a determination that KyphX® HV-R™ Bone Cement is substantially equivalent in technological characteristics and intended use to the predicates. The products have the same fundamental scientific technology in their chemical composition, material properties, performance characteristics, and biocompatibility, and also have the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2004

Cindy Domecus
Vice President, Clinical Research and Regulatory Affairs
Kyphon Inc.
1221 Crossman Avenue
Sunnyvale, California 94089

Re: K041584
Trade/Device Name: KyphX® HV-R™ Bone Cement, Model C01A
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Codes: NDN
Dated: June 11, 2004
Received: June 14, 2004

Dear Ms. Domecus:

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,

Miriam C. Provost

for Celia M. Witten, PhD, MD
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): K041584

Device Name: KyphX® HV-R™ Bone Cement

Indications for Use:

KyphX HV-R bone cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemagioma and giant cell tumor.

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

Miriam C. Provost

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

510(k) Number K041584