510(k) Summary

SEP 17 2012

General Information

Classification	Class II
Regulation Number	21CFR 888.1100 21CFR 888.3027
Regulation Name	Arthroscope Cement/Bone Vertebroplasty
Product Code	HRX NDN
Trade Name	KMC Kyphoplasty System
Submitter	Shanghai Kinetic Medical Co., Ltd
Submitted by	Regulatory Strategies, Inc. 3924 Cascade Beach Road Lutsen, MN 55612 Tel: (218) 387-1559
Contact	Gregory Mathison President

Date Prepared: April 20, 2011

Indications for Use

The KMC Kyphoplasty System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Predicate Devices

K061222	Kyphx Inflatable Bone Tamp	Kyphon Inc
K103231	Kyphon Inflation Syringe	Kyphon Inc

Device Description

KMC Kyphoplasty System consists of five components:

- Balloon Catheter
- Tool Kit
- Puncture Needle
- Balloon Catheter Syringe Pump
- Kyphoplasty Multifunctional Tool

The Kyphoplasty Multifunctional Tool can be substituted for the Puncture Needle and Kyphoplasty Tool Kit.

Sterilization

The system is provided sterile and is for single use only. The ETO gas sterilization process is validated with a resulting sterility assurance level (SAL) of 10^{-6}.

ETO residual testing was also performed and the products met specification.

Packaging

The components are placed in a thermoformed PETG/PET tray with a heat sealed Tyvek lid. The sealed tray is placed in a Tyvek flexible peel pouch and heat sealed. The heat sealed pouches are placed in white shelf cartons and then packaged in a corrugated shipper box. Expiration dating testing was conducted using the industry standard ASTM method for accelerated aging and real-time aging was also performed.

Materials

All materials used in the manufacture of the KMC Kyphoplasty System are suitable for this use and have been used in s previously cleared products.

Testing

Product testing was performed on final sterilized devices. Testing was completed, including: dimensional, inflation/deflation, balloon size and system compatibility. All testing met the acceptance criteria.

Biocompatibility testing was performed per ISO10993 as required for a temporary bone/tissue contacting device. All materials were found to be biocompatible and suitable for this use.

Clinical Evaluation

The KMC Kyphoplasty system was evaluated in a multicenter study. A total of 25 patients were treated at two sites. The conclusions from the study show the system performed per specification when used according to the instructions for use.

Summary of Substantial Equivalence

The KMC Kyphoplasty System is equivalent to the features of the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 17 2012

Shanghai Kinetic Medical Company, Limited
% Regulatory Strategies, Incorporated
Mr. Gregory Mathison
President
3924 Cascade Beach Road
Lutsen, Minnesota 55612

Re: K113742
Trade/Device Name: KMC Kyphoplasty System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: August 20, 2012
Received: August 29, 2012

Dear Mr. Mathison:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K113742

Device Name: KMC Kyphoplasty System

Indications for Use:

The KMC Kyphoplasty System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K113742