

JAN 24 2014

**510(K) SUMMARY AS REQUIRED BY 21 CFR 807.92****510(k) Owner:**

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**510(k) Contact:**

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**Date Prepared:** January 23, 2014

**Device Trade Name:** Kiva® VCF Treatment System

**Common Name:** Polymethylmethacrylate (PMMA) Bone Cement

**Classification Name:** Polymethylmethacrylate (PMMA) Bone Cement (21 CFR 888.3027)

**Device Product Code:** NDN, LOD

**Predicate Device(s):** The Kiva® VCF Treatment System is substantially equivalent to the following devices:

<b>Device</b>	<b>Manufacturer</b>	<b>510(k)</b>
StaXx™ FX System	SpineWave, Inc	K063606
Benvenue VCF Osteo Coil System	Benvenue Medical, Inc	K070293
KyphX® HV-R™ Bone Cement	Kyphon, Inc. (Medtronic)	K041584
KyphX® Inflatable Bone Tamp	Kyphon, Inc. (Medtronic)	K010246

**Device Description:**

The Kiva® VCF Treatment System is provided as a sterile, single use, implantable device which may be used in percutaneous procedures for the reduction and treatment of spinal fractures. The device consists of an implant, a deployment system for the implant, and a set of accessory access instruments. The deployment system component is a single-use, non-implantable device that is used to properly position and deliver the implant. It consists of a nitinol Kiva Coil, which is guided through a deployment cannula into the bone via a hand-operated mechanism. The Kiva Implant, made from PEEK Optima with barium sulfate for radiopacity, is guided over the nitinol Kiva Coil. As the Kiva Implant is pushed over the Kiva Coil, it reduces the fracture via height distraction of the vertebral body. Once the Implant is placed into the vertebral body, PMMA bone cement is deployed into the Kiva Implant. The Kiva Implant contains the PMMA bone cement and helps minimize posterior extravasation. A collection of manual surgical orthopedic instrumentation (Class I needles, stylets, cannulas) is used to gain access to the vertebral body at the start of the procedure, then again later for bone cement deployment.

**Statement of Intended Use:**

The Kiva® VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

**Sterilization:**

The Kiva® VCF Treatment System is terminally sterilized via irradiation according to the requirements of ANSI/AAMI/ISO 11137 to ensure a sterility assurance level (SAL) of  $10^{-6}$ .

**Biocompatibility:**

The materials comprising the Kiva® VCF Treatment System (implant, deployment system, and access instrumentation) have been evaluated and tested for biocompatibility according to applicable requirements of ANSI/AAMI/ISO 10993. Results demonstrated that the Kiva® VCF Treatment System is biocompatible.

**Non-Clinical/Mechanical Testing:**

The safety and performance of the Kiva® VCF Treatment System have been substantiated through extensive non-clinical mechanical testing. Results of the testing confirm that the Kiva® VCF Treatment System can reliably perform as intended.

**Clinical Performance Discussion:**

A clinical trial was conducted under an approved IDE. The study is titled Kiva® System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial (KAST trial). This was a prospective, multi-center, randomized, controlled study designed to evaluate the safety and effectiveness of the Kiva® VCF Treatment System in comparison to balloon kyphoplasty in the treatment of osteoporotic vertebral compression fractures (VCF). The primary endpoint was a composite of reduction in pain, maintenance or improvement in function in the absence of device related serious adverse events. Secondary endpoints include vertebral height restoration, cement volume, quality of life, ambulatory status, subject satisfaction, cement extravasation, device or cement migration, and subsequent fracture. A total of 300 subjects were enrolled at 21 sites in the US, Canada, and Europe. The results demonstrate the safety and effectiveness of the Kiva® VCF Treatment System and support substantial equivalence to predicate devices.

**Substantial Equivalence:**

The rationale for substantial equivalence of the Kiva® VCF Treatment System to cited predicates is summarized in the following bullet points:

- A substantial part of this device (Kiva Coil and Deployment System) is the cleared Benvenue VCF Osteo Coil System.
- The implantable PEEK Optima Kiva Implant part of the device is substantially equivalent to the stackable PEEK wafers of the Spine Wave StaXx™ FX device.
- The Kiva® VCF Treatment System reduces compression fracture via height distraction as do the predicate devices.
- The Kiva® VCF Treatment System functions in concert with PMMA bone cement to achieve fracture reduction and treatment as do the predicate devices. The following table describes and shows similarities of the indications for use among the predicate devices and the Kiva® VCF Treatment System.

Device	Indications for Use
StaXx™ FX System	The StaXx™ FX System is indicated for use in the reduction of spinal fractures. It is intended to be used in combination with Stryker Spineplex Radiopaque Bone Cement.
Benvenue VCF Osteo Coil System	The Benvenue VCF Osteo Coil System is indicated for the treatment of pathological compression fractures of the vertebral body that may result from osteoporosis, benign lesions, and/or malignant lesions, by creating channels in the existing spinal bone structure for the flow of PMMA bone cement.
KyphX® HV-R™ Bone Cement	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 hemangioma and giant cell tumor.
KyphX® Inflatable Bone Tamp	KyphX® Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon Kyphoplasty with KyphX® HV-R™ Bone Cement), hand, tibia, radius and calcaneus.
Kiva® VCF Treatment System	The Kiva® VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

- The extensive non-clinical and clinical testing performed on this device provides support that the Kiva® VCF Treatment System performs as intended and presents no different questions of safety or effectiveness.

The Kiva® VCF Treatment System device technological characteristics compared to predicate devices, indications for use compared with predicate devices, non-clinical test results, and clinical data demonstrate that the Kiva® VCF Treatment System is safe, effective, performs as intended, and is substantially equivalent to the currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 24, 2014

Benvenue Medical, Incorporated  
% Ms. Cindy Domecus, Regulatory Affairs Consultant  
Principal  
Domecus Consulting Services LLC  
1171 Barroilhet Drive  
Hillsborough, California 94010

Re: K132817

Trade/Device Name: Kiva<sup>®</sup> VCF Treatment System  
Regulation Number: 21 CFR 888.3027  
Regulation Name: Polymethylmethacrylate (PMMA) bone cement  
Regulatory Class: Class II  
Product Code: NDN, LOD  
Dated: January 6, 2014  
Received: January 7, 2014

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. 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

Page 2 – Ms. Cindy Domecus

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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

**Lori A. Wiggins**

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

Enclosure

#### 4. INDICATIONS FOR USE STATEMENT

**510(k) Number (if known):** K132817

**Device Name:** Kiva® VCF Treatment System

**Indications for Use:**

The Kiva® VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Laurence D. Coyne -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K132817