

510(k) Summary**Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared**

Submitter's Name: Crosstrees Medical, Inc.
Address: 4735 Walnut Street, Suite E
Boulder, CO 80301
Telephone: 720-880-5811
Fax: 303-484-6099
Contact Person: Robert Scribner
Telephone: 720-880-5811
Date Prepared: July 24, 2013

AUG 09 2013

Name of Device and Name/Address of Sponsor

Crosstrees® PVA Pod Device

Common Name

Bone Cement Delivery Device

Classification Name

888.3027 – Cement, Bone, Vertebroplasty
888.1100 – Arthroscope

Predicate Devices

Ascendx Spine, Inc. Ascendx VCF Repair System

Intended Use

The Crosstrees® PVA Pod device is intended to provide surgeons with a percutaneous means to deliver bone cement to painful pathologic compression fractures of the vertebral body in levels T4-L5 of the thoracic and lumbar spine. Pathologic fractures of the vertebral body may be caused by osteoporosis. It is intended to be used in combination with Crosstrees Fortibrae® Bone Cement when delivered by the Crosstrees CDrive® Bone Filler Delivery System.

Device Description

The Crosstrees® PVA Pod device is designed to deliver bone cement to the fractured vertebral body in a controlled manner without the need for an additional permanent implant other than the bone cement. The device consists of a shaft assembly for delivery of PMMA cement to a fabric barrier. Following cement delivery, the fabric barrier is opened and withdrawn from the vertebral body. The Crosstrees® PVA Pod device is made from a variety of materials commonly used in orthopedic and radiological procedures including stainless steel and polymers. The device is available in either a 2.0 mL or 3.0 mL fill capacity. The device is provided with a number of class I tools that are used for surgical access and delivery of the Pod to the surgical site, as well as preparation and delivery of bone cement.

Substantial Equivalence

The Crosstrees® PVA Pod device is substantially equivalent to the predicate devices, Ascendx Spine, Inc.'s Ascendx VCF Repair System (K100404). The Crosstrees® PVA Pod device has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate device. The minor technological differences between the Crosstrees® PVA Pod device and the predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Crosstrees® PVA Pod device provides appropriate mechanical strength for its intended use and performs as intended. Thus, the Crosstrees® PVA Pod device is substantially equivalent.

Performance Data

In support of this 510(k) Premarket Notification, Crosstrees Medical has conducted bench testing to demonstrate that the Crosstrees® PVA Pod device provides adequate mechanical strength for its intended use. In all instances, the Crosstrees® PVA Pod device functioned as intended.

A list of the tests performed to support substantial equivalence is provided below:

- Functional device and instrumentation testing
- Biocompatibility in accordance with ISO 10993
- Sterilization validation of device and instruments
- Shelf life testing

Summary of Clinical Evaluation

The Crosstrees® Percutaneous Vertebral Augmentation System ("PVA device" or "PVA Pod") was evaluated in a prospective, single arm, IDE clinical trial in adult patients with acute vertebral body compression fractures. The study objective was to evaluate the safety and efficacy of the PVA Pod in the delivery of the Crosstrees® Fortibrae Bone Cement® ("Fortibrae bone cement" or "bone cement") in the treatment of pathologic fractures (1-3 levels) of the vertebral column (T4-L5) in adult subjects. The study protocol as approved in the IDE specified performance criteria for two primary study endpoints based on a historical literature control. The study successfully met these performance criteria and demonstrated an excellent safety and efficacy profile for the product.

Only subjects meeting all of the inclusion criteria and none of the exclusion criteria were to be enrolled into the trial. Total enrollment for the study was 135 subjects (including 111 U.S. subjects), with 133 subjects included in the analysis population. The following were included as primary endpoints, evaluated at 6 months and 12 months post-procedure.

- Clinically significant improvement in pain (defined as improvement ≥ 2 cm from baseline as measured by 10 cm Visual Analog Scale (VAS)) (In this scale, 0 means "no pain" and 10 is "Severe pain". A difference of at least 2 cm compared to baseline is regarded as clinically relevant.);
- Freedom from cement leakage;
- Absence of device-related adverse events; and
- Absence of device-related reoperations or revisions.

The vast majority of study subjects achieved clinically significant improvement in their VAS pain scores of at least 2 cm as compared to baseline at 6 months (94.5%) and 12 months (89.6%) post-operative.

No extravasation was observed in the large majority of study subjects. The leakage rates observed by the radiographic core laboratory and the Investigator were low; extravasation was reported in 15.0% (20/133) of subjects in the core laboratory's conservative assessment of post-operative X-rays. Leakage was identified intra-operatively in 9.0% (12/133) of subjects by the Investigator. None of the leaks were symptomatic.

Regarding the third and fourth primary endpoints, none of the reported device-related adverse events in the study were considered serious and most of the device-related adverse events reported involved asymptomatic cement extravasation. Furthermore, no revisions or reoperations occurred at the index level in any of the study subjects through study follow-up of 12 month post-operative.

The study also included an Individual Patient Success composite endpoint, evaluating clinically significant pain improvement, freedom from extravasation, maintenance or improvement in neurological status, absence of device-related serious adverse events, absence of device-related revisions or reoperations, and absence of device-related adverse events. The large majority of study subjects (74.8%, 83/111) demonstrated Individual Patient Success at 12 months.

With respect to safety, through the 12 month post-operative visit, relatively few patients were observed to have a new fracture at an adjacent or remote level, including at 6 months (8.5% new adjacent level vertebral body fractures, 3.9% new remote vertebral body fractures compared to baseline) and 12 month (9.2% new adjacent level vertebral body fractures, 3.8% new remote level vertebral body fractures compared to baseline). Importantly, only 1 new fracture occurred between the 6 and 12 month visit, a T12 fracture secondary to a fall, reported in patient 04-008 at 10 months post-operative. Index level refracture, as identified by post-operative radiographic review, occurred in 17.9% of all treated levels through 12 months. None of these refractures were identified based on symptoms and none required treatment.

Overall, observed rates of adverse event occurrence demonstrated a good safety profile for the PVA Pod. No subjects experienced a device-related serious adverse event, and there were no device-related revisions or re-operations and no unanticipated adverse device effects.

The results of the study demonstrate the favorable safety and effectiveness profile for the PVA Pod device. The PVA Pod device successfully met both protocol-defined hypotheses for clinically significant VAS pain reduction and an acceptable rate of cement extravasation, demonstrating the effectiveness of the device for its intended use as compared to the prospectively defined historical control.



August 9, 2013

Crosstrees Medical, Incorporated
% Hogan Lovells US LLP
Ms. Janice Hogan
Attorney
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K130089

Trade/Device Name: Crosstrees[®] PVA Pod
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, LOD
Dated: June 21, 2013
Received: June 21, 2013

Dear Ms. Hogan:

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. Janice Hogan

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,

Erin I. Keith

For

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

Enclosure

Indications for Use Form

510(k) Number (if known): K130089

Device Name: Crosstrees® PVA Pod

Indications for Use:

The Crosstrees® PVA Pod device is intended to provide surgeons with a percutaneous means to deliver bone cement to painful pathologic compression fractures of the vertebral body in levels T4-L5 of the thoracic and lumbar spine. Pathologic fractures of the vertebral body may be caused by osteoporosis. It is intended to be used in combination with Crosstrees Fortibrae® Bone Cement when delivered by the Crosstrees CDrive® Bone Filler Delivery System.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) _____

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130089

Page 1 of 1