K110185

FEB 16 2011

510(k) Summary

ArthroCare Corporation
ArthroCare Parallax Contour Vertebral Augmentation Device – *enhanced*

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	January 20, 2011

Device Description

Trade Name:	ArthroCare Parallax Contour Vertebral Augmentation Device - *enhanced*
Generic/Common Name:	Polymethylmethacrylate (PMMA) Bone Cement
Classification Name:	Class II; Polymethylmethacrylate (PMMA) bone cement (Section 888.3027); Class 1 Cement dispenser (Section 888.4200); and Class I Orthopedic Manual Instrument (Section 878.4540)
Predicate Device: ArthroCare Parallax Contour Vertebral Augmentation Device	K100479 (cleared September 21, 2010)

Product Description

The ArthroCare Parallax Contour Vertebral Augmentation Device - *enhanced* is used to disrupt cancellous bone and create a void in the vertebral body and fill the void with Parallax Acrylic Resin (bone cement) during kyphoplasty or vertebral augmentation procedures.

Intended Use

The ArthroCare Parallax Contour Vertebral Augmentation Device - *enhanced* when used with the access needle kits are indicated for use during kyphoplasty or vertebral augmentation procedures to create a void in the vertebral body and fill the void with Parallax Acrylic Resin (bone cement). The painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma.

Substantial Equivalence

This Special 510(k) proposes modifications to the dimensional specifications, material, and labeling of the ArthroCare Parallax Contour Vertebral Augmentation Device. The indications for use, technology, principle of operation, and sterilization of the ArthroCare Parallax Contour Vertebral Augmentation Device - *enhanced* remain the same as in the predicate device.

Summary of Safety and Effectiveness

In establishing substantial equivalence to the predicate device, ArthroCare compared the indications for use, materials, dimensional specifications, and performance of the subject device to the predicate device. Functional performance testing of the device included torque, insertion and withdrawal, flexure, device attachment/deployment/ removal, and mechanical displacement of bone have been completed to demonstrate the mechanical characteristics and performance remain the same as the predicate device. The proposed modifications to the ArthroCare Parallax Contour Vertebral Augmentation Device – *enhanced* are not substantial changes, and do not significantly affect the safety or efficacy of the device.

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

ArthroCare Corporation
% Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085

FEB 16 2011

Re: K110183
Trade/Device Name: ArthroCare® Parallax® Contour® Vertebral Augmentation Device – *enhanced*
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, OAR, HXG
Dated: January 20, 2011
Received: January 21, 2011

Dear Ms. Defiesta-Ng:

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,

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

Enclosure

Indications for Use Statement

510(k) Number: K_____

Device Name: ArthroCare® Parallax® Contour® Vertebral Augmentation Device - *enhanced*

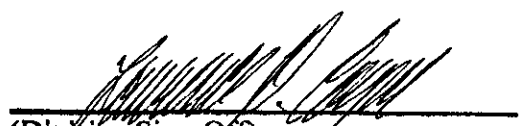
Indications for use:

The ArthroCare® Parallax® Contour® Vertebral Augmentation Device – *enhanced* when used with the access needle kits are indicated for use during kyphoplasty or vertebral augmentation procedures to create a void in the vertebral body and fill the void with Parallax® Acrylic Resin (bone cement). The painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma.

Prescription Use (Part 21 CFR 801 Subpart D)	X	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)



(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110183