K051820

510(k) Summary of Safety and Effectiveness
ArthroCare Corporation
Parallax® EZFlow™ Cement Delivery System

General Information

Manufacturer:	ArthroCare, Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	July 1, 2005

Device Description

Classification:	Cement Dispenser: Class I Exempt per 21 CFR 888.4200
Trade Name:	Parallax® EZFlow™ Cement Delivery System
Device Code:	OAR and KIH
Generic/Common Name:	Cement Dispenser

Predicate Devices

Parallax® Cement Injector Kit	K980064

Intended Use

Parallax® EZFlow™ Cement Delivery System is intended for use with Parallax Acrylic Resin with TRACERS or Parallax Acrylic Resin with TRACER Ta for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Product Description

Parallax® EZFlow™ Cement Delivery System is a delivery system for the Parallax Acrylic Resin with TRACERS and Parallax Acrylic Resin with TRACERS Ta. It is designed to provide surgeons with a means to inject Parallax Acrylic Resin with TRACERS or Parallax Acrylic Resin with TRACERS Ta for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. The EZFlow Cement Delivery System does not contain any bone cement material, as this system only consists of general instruments. All of the system components are manual, single-use disposable instruments.

Substantial Equivalence

In establishing substantial equivalence, ArthroCare evaluated the indications for use, functional testing, and prospective clinical data to demonstrate equivalence to the predicate devices. We believe the EZFlow Cement Delivery System is substantially equivalent to the currently marketed device in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2007

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

Re: K051820
Trade/Device Name: Parallax EXFlow Cement Delivery System
Regulation Number: 21 CFR 888.4200
Regulation Name: Cement Dispenser
Regulatory Class: Class I Exempt
Product Code: OAR
Dated: September 6, 2005
Received: September 6, 2005

Dear Ms. Defiesta-Ng:

This letter corrects our exempt letter of September 6, 2005.

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.

We note that your device exceeded the Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 CFR Part 888.9), and therefore required the submission and clearance of a premarket notification prior to commercial distribution in the United States. Future devices of this same type, that meet the exemption criteria and do not exceed the limitations of exemptions found in 21 CFR Part 888.9 will be exempt from the premarket notification requirements of the Act.

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 240-276-0120. 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,

Barbara Melkerson

Mark N. Melkerson
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): K051820

Device Name: Paralax® EXFlow™ Cement Delivery System

Indications For Use:

Parallax® EZFlow™ Cement Delivery System is intended for use with Parallax Acrylic Resin with TRACERS or Parallax Acrylic Resin with TRACERS Ta for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)