K072133

CardinalHealth

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NOV 2 0 2007

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
AVAflex Vertebral Augmentation Needle

Sponsor:	Cardinal Health 1430 Waukegan Road MPKB McGaw Park, IL 60085
Regulatory Affairs: Contact	Sharon Nichols
Telephone:	(847) 578-6610
Date Summary Prepared:	November 2007
Common Name:	AVAflex Vertebral Augmentation Needle
Regulation Description:	Primary - Cement, Bone Vertebroplasty Secondary - Tamp, Cement Dispenser
Device Class and Regulation Number:	Class II per 21CFR §888.3027, Procode NDN Class I per §888.4540, Procode HXG and §888.4200, Procode OAR
Predicate Devices:	Cardinal Health Chroma-Line Cervical and Lumbar Spine Curettes, Class I exempt Kyphon, Inc., Kyphx Latitude Curette, Class I exempt Medtronic Sofamor Danek, Arcuate Vertebral Augmentation System, K063248

Description:	The AVAflex Vertebral Augmentation Needle is a device used to disrupt cancellous bone by scraping and scoring the bone as and creating a void within a vertebral body. After the bone is disrupted, Radiopaque Bone Cement is injected through the AVAflex Vertebral Augmentation Needle to fill the previously created void.
Intended Use:	The AVAflex Vertebral Augmentation Needle is used during a vertebroplasty to fill a fractured vertebral body with Radiopaque Bone Cement manufactured by Cardinal Health. The painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma. . The AVAflex Vertebral Augmentation Needle is used during a kyphoplasty to scrape and score bone in the spine to create a void within a fractured vertebral body and fill the void with Radiopaque Bone Cement manufactured by Cardinal Health. The painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma.
Summary of Technological Characteristics:	The proposed device and the predicate device are composed of the same or similar design, materials and the manufacturing characteristics.
Summary of testing:	All materials used in the fabrication of the Vertebral Augmentation Needle were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.
Non-Clinical Testing:	Performance testing demonstrated that the proposed device is substantially equivalent to the currently marketed curettes with regard to functional characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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CardinalHealth
% Ms. Sharon Nichols
Regulatory Affairs
1430 Waukegan Road
McGwa Park, IL 60085-6787

Re: K072133
Trade/Device Name: AVAflex Vertebral Augmentation Needle
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN, HXG, OAR
Dated: October 25, 2007
Received: October 26, 2007

Dear Ms. Nichols:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-3464. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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Indication for Use

510(k) Number (if known): K072133

Device Name: AVAflex Vertebral Augmentation Needle

Indications For Use: The AVAflex Vertebral Augmentation Needle is used during a vertebroplasty to fill a fractured vertebral body with Radiopaque Bone Cement manufactured by Cardinal Health. The painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma.

The AVAflex Vertebral Augmentation Needle is used during a kyphoplasty to scrape and score bone in the spine to create a void within a fractured vertebral body and fill the void with Radiopaque Bone Cement manufactured by Cardinal Health. The painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma.

Prescription Use _X_ or Over-The Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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