K093463

CareFusion

FEB 2 6 2010

CareFusion
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.578.6610
FAX: 847.785.2506

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Inflatable Bone Tamp

Sponsor:	CareFusion 1500 Waukegan Road MPWM McGaw Park, IL 60085
Regulatory Affairs: Contact	Sharon Nichols
Telephone:	(847) 578-6610
Date Summary Prepared:	November 2009
Common Name:	Inflatable Bone Tamp
Regulation Description:	Primary - Arthroscope Secondary - Cement, bone, vertebroplasty
Device Class and Regulation Number:	Class II per 21CFR §888.1100, Procode HRX: Class II per 21CFR §888.3027, Procode NDN:
Predicate Devices:	Cardinal Health Inflatable Bone Tamp, K090211 Kyphx Inflatable Bone Tamp, K041454, K981251 Radiopaque Bone Cement, K043518

Description:	The Inflatable Bone Tamp (IBT) was designed for use in Balloon kyphoplasty. The balloon serves to create a cavity in the vertebral body, thereby reducing the fracture and preventing cement leakage, while still allowing for cement interdigitation. The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon catheter provides a conduit through which the physician can inflate the balloon at the distal end of the catheter. The wire stiffener provides stiffness to the balloon catheter to facilitate insertion through the access cannula
Intended Use:	Intended for the reduction and fixation of fractures in cancellous bone in the spine for kyphoplasty (for use with CareFusion Radiopaque Bone Cement).
Summary of Technological Characteristics:	The proposed device and the predicate devices are composed of the same or similar design, materials and manufacturing characteristics.
Summary of testing:	All materials used in the fabrication of the Inflatable Bone Tamp were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". These materials also were evaluated 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 predicate devices with regard to functional characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

CareFusion
% Ms. Sharon Nichols
Regulatory Affairs Manager
1500 Waukegan Road
McGaw Park, Illinois 60085

FEB 2 3 2010

Re: K093463
Trade/Device Name: Inflatable Bone Tamp
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN, HRX
Dated: February 3, 2010
Received: February 4, 2010

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. 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

CareFusion
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.578.6610
FAX: 847.785.2506

Indication for Use

510(k) Number (if known):	unknown at this time
Device Name:	Inflatable Bone Tamp
Indications For Use:	Intended for the reduction and fixation of fractures in cancellous bone in the spine for kyphoplasty (for use with CareFusion Radiopaque Bone Cement).

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)

FOR M. MELKERSON

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

510(k) Number K093463