



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

CareFusion  
Ms. Joy Greidanus  
Manager, Regulatory Affairs  
75 North Fairway Drive  
Vernon Hills, Illinois 60061

November 24, 2015

Re: K151125  
Trade/Device Name: AVAflex Vertebral Balloon System  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: Class II  
Product Code: HRX, NDN  
Dated: September 30, 2015  
Received: October 2, 2015

Dear Ms. Greidanus:

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 Parts 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 contact the Division of Industry and Consumer Education 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" (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 Industry and Consumer Education 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 -S**

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved OMB No 0910-0120  
Expiration Date January 31, 2017  
See PRA Statement below

**Indications for Use**

510(k) Number (if known)  
Unknown K151125

Device Name

AVAflex Vertebral Balloon System

Indications for Use (Describe)

Intended for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine for kyphoplasty (for use with CareFusion Radiopaque Bone Cement).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) SUMMARY K151125

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

<b>SUBMITTER INFORMATION</b>	
Name	CareFusion
Address	75 North Fairway Drive, Vernon Hills IL 60061 USA
Phone number	(847) 362-8103
Fax number	(312) 949-0583
Establishment Registration Number	1423507
Name of contact person	Joy Greidanus
Date prepared	September 30, 2015
<b>NAME OF DEVICE</b>	
Trade or proprietary name	AVAflex Vertebral Balloon System
Common or usual name	Inflatable Bone Tamp
Classification name	Arthroscope
Classification panel	Orthopedic
Regulation	Class II per 21CFR §888.1100, Procode HRX Class II per 21CFR §888.3027, Procode NDN
Legally marketed device(s) to which equivalence is claimed	CareFusion Inflatable Bone Tamps, K131824 Radiopaque Bone Cement, K043518
Reason for 510(k) submission	Modifications to device
Device 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.
Intended use of the device	Intended for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine for kyphoplasty (for use with CareFusion Radiopaque Bone Cement).

<b>SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE</b>		
Characteristic	New Device	Predicate CareFusion Vertebral Balloon K131824
Compatible cannula size	11G	10G
Balloon inflation medium	60% contrast recommended	60% contrast recommended
Markers	Radiopaque	Radiopaque
Balloon shape	Cylindrical	Cylindrical
Maximum recommended inflation pressure	400 psi (27 ATM)	400 psi (27 ATM)
Maximum recommended inflation volume	3-6 mL	4-8 mL
<b>PERFORMANCE DATA</b>		
<b>SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE</b>		
<b>Performance Test Summary-New Device</b>		
Characteristic	Standard/Test/FDA Guidance	Results Summary
Inflation pressure	Constrained burst test	The balloon catheters exceeded the requirements for the minimum burst pressure in a constrained environment.
Inflation volume	Unconstrained burst test	The balloon catheters exceeded the requirements for the minimum burst volume in an unconstrained environment.
Balloon double wall thickness	Calibrated measurement	The double wall thickness of the balloons was substantially equivalent to that of the predicate device.
Simulated use	Cadaver	Cadaveric simulated use testing demonstrated substantial equivalence in performance.
<b>SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION</b>		
N/A – No clinical tests were conducted for this submission.		
<b>CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA</b>		
The results of the non-clinical tests show that the CareFusion Flexible IBT System meets or exceeds all performance requirements, and is substantially equivalent to the predicate device.		