CareFusion

OCT 18 2012

# 510(k) SUMMARY K121849

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

| **SUBMITTER INFORMATION** | |
|---|---|
| Name | CareFusion |
| Address | 1500 Waukegan Road MPWM, McGaw Park, IL 60085 USA |
| Phone number | (847) 473-7404 |
| Fax number | (847) 473-7790 |
| Establishment Registration Number | 1423507 |
| Name of contact person | Joy Greidanus |
| Date prepared | October 17, 2012 |
| **DESCRIPTION OF DEVICE** | |
| Trade or proprietary name | Pleurx Pleural Catheter System |
| Common or usual name | Pleural Drainage Catheter |
| Classification name | Patient Care Suction Apparatus |
| Classification panel | Anesthesiology |
| Regulation | Class II per 21CFR §870.5050, Procode DWM |
| Product Code(s) | Multiple |
| Legally marketed device(s) to which equivalence is claimed | CareFusion Pleurx Catheter Systems: K112831 & K113854<br>Bard Aspira Pleural Drainage System: K110409<br>Martech (MEDCOMP) Valved Tearaway Introducer: K090394<br>Greatbatch (MedAmicus) Incorporated FlowGuard Peelable Introducer: K040150 |
| Reason for 510(k) submission | Expanding the indications for use and adding accessories. |
| Device description | The Pleurx Pleural Cather System provides patients with a convenient method to relieve pleural effusion symptoms at home. The primary components of the Pleurx Catheter System are the Pleurx Pleural Catheter and the Pleurx Drainage Kits. |

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|---|---|
| Intended use of the device | The Pleurx Pleural Catheter Kits are indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for 1) the palliation of dyspnea due to pleural effusion and 2) providing pleurodesis (resolution of the pleural effusion).<br><br>The Pleurx Drainage Kits and Drainage Line Set are indicated for use only with the Pleurx Catheter for intermittent drainage. The Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.<br><br>The Pleurx Dressing Kits are indicated for dressing of a catheter and exit site.<br><br>The Pleurx Catheter Access Kit is intended to provide access to the Pleurx Catheter for aspiration and catheter maintenance.<br><br>The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the pleural space.<br><br>The Valved Peelable Introducers are intended for use in the percutaneous insertion of a catheter into the pleural space. |

**SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE**

| **Characteristic** | **New Device** | **Predicates:**<br>CareFusion Pleurx Catheter System: K112831 & K113854<br>Bard Aspira Pleural Catheter System K110409<br>Martech (MEDCOMP) Valved Tearaway Introducer: K090394<br>Greatbatch (MedAmicus) Incorporated FlowGuard Peelable Introducer: K040150 |
|---|---|---|
| Catheter Description | Internal: fenestrations, radiopaque markings & cuff<br>External: valve | Same |
| Method | Percutaneously tunneled - indwelling | Same |
| Valved Peelable Introducers description | Peelable sheath, dilator, hub, valve | Same |
| Access Kit Description | Provides access for sample aspirations and catheter maintenance | Same |
| Insertion Stylet | Reduces fluid loss, provides stiffening | Same |

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| PERFORMANCE DATA | |
|---|---|
| **SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE** | |
| **Performance Test Summary** | |
| Characteristic | Standard/Test/FDA Guidance |
| Biocompatibility | AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of Medical Devices Part 1: Evaluation and Testing |
| Biocompatibility | AAMI/ANSI/ISO 10993-3: 2003 (R) 2009 Biological Evaluation of Medical Devices – Part 3 Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity |
| Biocompatibility | AAMI/ANSI/ISO 10993-4: 2002 (R) 2009 Biological Evaluation of Medical Devices – Part 4 Selection of Tests for Interaction with Blood |
| Biocompatibility | AAMI/ANSI/ISO 10993-5: 2009 Biological Evaluation of Medical Devices – Part 5 Tests for In Vitro Cytotoxicity |
| Biocompatibility | AAMI/ANSI/ISO 10993-6: 2007 (R) 2010 Biological Evaluation of Medical Devices – Part 6 Tests for Local Effects After Implantation |
| Residuals | AAMI/ANSI/ISO 10993-7:2008 Biological evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals |
| Biocompatibility | AAMI/ANSI/ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10 Tests for Irritation and Skin Sensitivity |
| Biocompatibility | AAMI/ANSI/ISO 10993-11: 2006 Biological Evaluation of Medical Devices – Part 11 Tests for Systemic Toxicity |
| Biocompatibility | 'USP <661> Containers – Plastics, Physiochemical Tests |
| Performance | EN 1617:1997 Sterile Drainage Catheters and Accessory Devices for Single Use |
| Performance | EN 1618:1997 Catheters Other Than Intravascular Catheters – Test Methods for Common Properties |
| Performance | ISO 11070 Sterile, Single-use Intravascular Catheters |
| Performance | ANSI/AAMI/ISO 11607-1,2:2006 Packaging for Terminally Sterilized Medical Devices |
| Performance | ASTM F1980-07 Accelerated Aging of Sterile Barrier Systems |
| Performance | ISO 11138-1,2:2006 Sterilization of healthcare products - Biological Indicators |
| Performance | ISO 11737-1,2:2006 Sterilization of Medical Devices – Microbiological Methods Part 1 & 2 |
| Performance | ISO 11135:2007 Medical Device, Validation and Routine Control of Ethylene Oxide Sterilization |
| Performance | AAMI TIR28:2009 Product Adoption and Process Equivalency for Ethylene Oxide Sterilization |
| **SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION** | |
| N/A – No clinical tests were conducted for this submission | |
| **CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA** | |
| The results of the non-clinical tests show that the CareFusion Pleurx Pleural Catheter System meets or exceed all performance requirements, and are substantially equivalent to the predicate devices. | |

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

OCT 18 2012

CareFusion
Ms. Joy Greidanus
Regulatory Affairs Manager
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K121849
Trade/Device Name: Pleurx Pleural Catheter System
Regulation Number: 21 CFR 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: II
Product Code: DWM
Dated: September 27, 2012
Received: September 28, 2012

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 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CareFusion

*1500 Waukegan Road*
*McGaw Park, Illinois 60085-6787*
*847.473.7404*
*FAX: 847.473.7790*

510(k) Number (if known): K121849

Device Name: Pleurx Pleural Catheter System

**Indications For Use:**

The Pleurx Pleural Catheter Kits are indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for 1) the palliation of dyspnea due to pleural effusion and 2) providing pleurodesis (resolution of the pleural effusion).

The Pleurx Drainage Kits and Drainage Line Set are indicated for use only with the Pleurx Catheter for intermittent drainage. The Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.

The Pleurx Dressing Kits are indicated for dressing of a catheter and exit site.

The Pleurx Catheter Access Kit is intended to provide access to the Pleurx Catheter for aspiration and catheter maintenance.

The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the pleural space.

The Valved Peelable Introducers are intended for use in the percutaneous insertion of a catheter into the pleural space.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)
And/Or Over-The Counter Use_____ (Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** K121849