K093817

JUL - 1 2010

510(k) Summary

Applicant:

Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92614
USA
Phone: 949.250-3837
Fax: 949.756-4408

Date:

May 21, 2010

Contact Persons:

Jason K. Lyon
Principal Project Manager, Regulatory Affairs

Irene Parker
Sr. Director of Regulatory Affairs

Proprietary Device Name:

RetroFlex 3™ Introducer Sheath Set

Common Device Name:

Catheter Introducer
(21 CFR 870.1340, Product Code DYB), and;

Classification:

Class II

Predicate Devices:

Edwards Lifesciences, LLC – Edwards Introducer Sheath
cleared under K031087

Guidant EndoVascular Surgery Group – ANCURE® Sheath
cleared under K003889

Manufacturer:

Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92614
USA

7.1 *Substantially Equivalent To:*

The RetroFlex 3 Introducer Sheath Set was evaluated for in-vitro performance and biocompatibility tests, which are outlined below. The physical characteristics and mode of use of the RetroFlex 3 Introducer Sheath is similar to the Edwards Introducer Sheath and the Ancure® Sheath, and are common in mode of operation, intended use, and dimensions. The devices have only slight variations to technological design and materials. These differences, however, do not alter the fundamental use of the products, which is to facilitate entry into the arterial vasculature.

Based on the data presented in this 510(k) Premarket Notification, the RetroFlex 3 Introducer Sheath Set is substantially equivalent to the predicate devices.

7.2 *Description of the Device Subject to Premarket Notification:*

The RetroFlex 3 Introducer Sheath Set is a hydrophilic delivery system used over a compatible 0.035" guidewire for the percutaneous introduction of intravascular devices. The RetroFlex 3 houses three (3) valves (a duckbill valve, a cross-slit valve, and a disc valve) to achieve hemostasis and is fitted with a three-way stopcock to allow infusion or aspiration of fluid. Each RetroFlex 3 Introducer Sheath Set contains a sheath, an introducer (or dilator), and a loader. The loader enables a device to enter into the sheath by bypassing all of the three valves within the sheath. The loader also contains a disc valve for hemostasis. The loader allows for larger devices to enter into the vascular system.

The RetroFlex 3 Introducer Sheath is for one-time use only, sold and packaged sterile. The table below identifies the model and sheath diameters. (**Table 7.2**).

Table 7.2 – RetroFlex 3™ Introducer Sheaths

Model No.	Sheath O.D.	Sheath I.D.
9120S23	25F	22F
9120S26	28F	24F

7.3 *Indications For Use:*

The RetroFlex 3 Introducer Sheath is intended for entry of interventional devices into the vascular system.

7.4 *Performance Data:*

The RetroFlex 3 Introducer Sheath was verified and tested according to performance testing standards ISO 10555-1:1997, Sec 4.5, *Sterile Single Use Intravascular Catheters*. The following tests have been conducted to demonstrate substantial equivalence to the predicate devices with respect to intended use, design, materials, and performance. The following non-clinical tests and biocompatibility tests were performed:

- Visual examination
- Dimensional verification

- Tensile strength
- Guidewire compatibility
- Hydrophilic coating test
- Packaging Integrity
- Sterilization Validation
- Biocompatibility
    - Medium Eluate Method (MEM)
    - Agar Overlay Method (AO)
    - Blood Compatibility Test Method
    - Mouse Systemic Injection
    - Rabbit Pyrogen (Chemical-Mediated) Test
    - Rabbit Intracutaneous Irritation
    - Guinea Pig Maximization Test
    - Complement Activation Test
    - Thrombogenicity (porcine model)

- Chemical
    - Material Verification
    - USP Physico-Chemical Test

7.5 Conclusion:

Based upon the non-clinical testing noted above and the data presented in the 510(k) Premarket Notification, the RetroFlex 3™ Introducer Sheath Set has met the requirements threshold to establish substantial equivalence to the predicate devices for market clearance.

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

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Edwards Lifesciences, LLC
c/o Mr. Jason K. Lyon
Principal Project Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K093877
Trade/Device Name: RetroFlex 3™ Introducer Sheath Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: June 25, 2010
Received: June 28, 2010

Dear Mr. Lyon:

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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Indications for Use

510(k) Number (if known): K093877

Device Name: RetroFlex 3™ Introducer Sheath Set

The RetroFlex 3™ Introducer Sheath Set is intended for entry of interventional devices into the vascular system.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093877