

510(k) Summary

MAR 15 2013

Submitter: Edwards Lifesciences LLC

Contact Person: Dannette Crooms, Manager, Regulatory Affairs
12050 Lone Peak Pkwy
Draper, UT 84020
(801) 565-6209

Date Prepared: October 22, 2012

Trade Name: Edwards Lifesciences® Femoral Access Arterial Cannulae

Classification Name: cardiopulmonary bypass vascular catheter, cannula or tubing
Class II (21 CFR §870.4210).

Predicate Devices

- K891576, Cleared October 5, 1989
- K905312, Cleared January 15, 1991
- K033463, Cleared July 28, 2004

Device Description:

The Edwards Femoral Access Arterial Cannulae with or without Duraflo® coating are wire-reinforced thin-wall polymer cannulae. The wire reinforcement is intended to prevent kinking during use.

The clear proximal section of the cannula is unreinforced for clamping and terminates in either a barbed connector for 1/4" or 3/8" tubing connection.

The cannulae are available in various sizes and lengths. Edwards Femoral Access Arterial Cannulae are available in a range of sizes with a variety of tip and hole configurations, including stainless steel and plastic tips. The cannulae tips are tapered for easy insertion.

Some cannulae feature incremental depth markings to aid in proper placement and positioning. As an additional aid to placement, the clear tip of some versions of the

cannula contains two radiopaque barium stripes for visualization. Some product codes may also include a suture ring.

Edwards Femoral Access Arterial Cannulae are intended to provide a means of perfusing blood into the body of a patient during cardiopulmonary bypass procedures.

Edwards Femoral Access Arterial Cannulae are also available with Duraflo® coating.

Intended Use:

Intended for femoral venous and arterial access during cardiopulmonary bypass (CPB).

Indications for Use:

Edwards Lifesciences Femoral Access Cannulae are intended for use in situations which require rapid femoral venous and arterial access for short-term (≤ 6 hours) cardiopulmonary bypass. Vessel access (venous or arterial) is left to the discretion of the physician.

Femoral Access Cannula may be used in pediatric populations or adult populations based on flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Comparative Analysis:

The basis for this submission is a clarification of the Indications for Use statement. No physical changes are being made to these devices. The subject devices have the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices. It has been demonstrated that the subject Femoral Access Arterial Cannulae are comparable to the predicate devices in fundamental scientific technology, material types, principles of operation, and functional performance evaluations. No new issues of safety or efficacy have been raised.

Functional/Safety Testing:

Bench and laboratory testing was performed and assures that the product meets its specifications per the table below. The performance testing met the acceptance criteria.

| Testing | Criteria |
|--|--|
| Sterility | Per ISO11135-1, Sterilization of health care products – Ethylene oxide - Part 1: |
| Ethylene oxide sterilization residuals | ISO 10993-7, Biological evaluation of medical devices - Part 7: |
| Biocompatibility | Per ISO 10993-1 for External communicating device, direct circulating blood path, duration ≤ 24 hours. |
| Conical Fittings | Fittings must be compatible with standard connections. |
| Dimensional Inspection | Confirmation of critical dimensions such as ID, OD and length. |
| Wire Encapsulation | Cannula body wire reinforcement shall be fully encapsulated. |
| Cannula Leak | Pressure drop must meet minimum requirement. |
| Kink | The cannulae shall not kink at a pre-determined diameter. |
| Cannula Crush | The cannulae must not crush at a pre-determined compression. |
| Cannula Collapse | The cannulae must not collapse at a pre-determined vacuum pressure. |
| Tensile | Confirmation of the bond strength of the catheter assembly must meet pre determined loads. |
| Cap removal force | Confirm cap removal force is within pre-determined limits. |

The Femoral Access Arterial Cannulae conform to the following standards:

- ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing.
- ISO 10993-7, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO11135-1, Sterilization of health care products – Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO14971, Medical devices – Application of risk management to medical devices

Conclusion:

The Femoral Access Arterial Cannulae are substantially equivalent to the cited predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 15, 2013

Edwards Lifesciences LLC
C/O Dannette Crooms
12050 Lone Peak Pkwy.
Draper, UT 84020

Re: K123298

Trade/Device Name: Femoral Access Arterial Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: February 15, 2013
Received: February 19, 2013

Dear Ms. Crooms:

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,

Matthew G. Hillebrenner

for
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

510(k) Number (if known): K123298

Device Name: Edwards Lifesciences Femoral Access Cannulae

Indications for Use:

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Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Matthew G. Hillebrenner