March 13, 2020

Edwards Lifesciences LLC
Anna Califato
Senior Specialist
One Edwards Way
Irvine, California 92614

Re: K200358
Trade/Device Name: Fem-Flex II Femoral Arterial Cannula, Fem-Flex II Femoral Venous Cannula, Femoral Venous Cannula, FemTrak Femoral Venous 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 12, 2020
Received: February 13, 2020

Dear Anna Califato:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200358

Device Name
Femoral Access Venous and Arterial Cannulae

Indications for Use *(Describe)*
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 cannulae 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person*:*	Anna Califato, Senior Specialist, Regulatory Affairs One Edwards Way Irvine, CA 92614 (949) 250-5083
Date Prepared:	February 12, 2020
Trade Name:	Fem-Flex II Femoral Arterial Cannula Fem-Flex II Femoral Venous Cannula Femoral Venous Cannula FemTrak Femoral Venous Cannula
Classification Name*:*	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass 21 CFR Part 870.4210, Product Code DWF, Class II
Predicate Device:	K140208 Femoral Access Venous and Arterial Cannulae
Device Description:	The Edwards Femoral Access Venous and Arterial Cannulae are wire-reinforced thin-wall polyurethane or PVC 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 ¼" or 3/8" tubing connection. The cannulae are available in various sizes and lengths. Each cannula is furnished with one, or in some cases two, dilator(s). In the case of cannulae supplied with two dilators, one is solid and the other is hollow. The hollow dilator will pass over guidewires up to 0.038" (0.97 mm) in diameter. The guidewire, when used, facilitates percutaneous insertion, or insertion under direct visualization. The cannulae tips are tapered for easy insertion. Some cannulae feature incremental depth markings to aid in proper placement and positioning. Some versions have, as an additional aid to placement, the clear tip section of the cannula contain two radiopaque barium strips for visualization. Edwards Femoral Access Cannulae are intended to provide a means of draining the blood flow (venous), or perfusing blood into the body (arterial) of a patient during

	cardiopulmonary bypass procedures. Each Edwards Lifesciences device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch.
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 cannulae 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.
Comparative Analysis:	The subject devices are comparable to the predicate devices in intended use, fundamental scientific technology, design, principles of operation, and functional performance as no changes have been made to the devices. The only changes being made are modifications to the Instructions for Use.
Functional/Safety Testing:	No functional/safety testing was performed for the Femoral Access Venous and Arterial Cannulae. The only changes being made are modifications to the Instructions for Use. The devices, with the proposed modification statements, have the identical design, materials, technology, and operating principles as the current legally marketed version of the devices, and as such no performance testing was conducted. The current legally marketed version of the Femoral Access Venous and Arterial Cannulae complies will all applicable design practices and regulations and was most recently cleared by FDA via K140208 (SE March 5, 2014) for modifications of its packaging.
Conclusion:	The Femoral Access Venous and Arterial Cannulae are identical, and therefore substantially equivalent to the named predicate device based on technological comparison, principle of operation, and intended use. There are no new questions of safety and effectiveness.