March 29, 2020

Edwards Lifesciences LLC
Diem Nguyen
Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K200499
Trade/Device Name: QuickDraw Venous Cannula (models QD22 and QD25)
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: February 25, 2020
Received: February 28, 2020

Dear Diem Nguyen:

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)*
K200499

Device Name
QuickDraw™ Venous Cannula, models QD22 and QD25

Indications for Use *(Describe)*
The QuickDraw venous cannula is indicated for use in patients undergoing cardiopulmonary bypass. The QuickDraw venous cannula serves to drain non-oxygenated blood from the venae cavae and/or right atrium during cardiopulmonary bypass.

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.

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

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Edwards

510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person*:*	Diem My Nguyen Specialist, Regulatory Affairs One Edwards Way Irvine, CA 92614 (949) 250-5124
Date Prepared:	February 25, 2020
Trade Name:	QuickDraw™ Venous Cannula, models QD22 and QD25
Classification Name*:*	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Predicate Device:	QuickDraw™ Venous Cannula, models QD22 and QD25
Device Description:	The Edwards Lifesciences QuickDraw venous cannula kit includes a wirewound cannula, introducer(s), guidewire, connector hub, and percutaneous insertion components. The cannula and introducer(s) have tapered tips to aid in insertion and advancement into the femoral vein. The cannula is marked at 5 cm intervals from the first marker band to indicate the depth of insertion. The soft, clear tubing near the barbed end of the cannula allows visualization of air and blood and provides a non-reinforced clamp site. The cannula connector is a 3/8 in. (9.5 mm) barbed connector. The introducers accept a 0.038 in. (0.97 mm) guidewire for assistance in cannula insertion. The connector hub secures and immobilizes the introducer within the cannula for easier, one-person insertion of the cannula/introducer assembly. For percutaneous insertion, percutaneous insertion components are provided.
Indications For Use:	The QuickDraw venous cannula is indicated for use in patients undergoing cardiopulmonary bypass. The QuickDraw venous cannula serves to drain non-oxygenated blood from the venae cavae and/or right atrium during cardiopulmonary bypass.
Comparative Analysis:	The subject device is identical as the predicate device with only the addition of a contraindication and a warning to the Instructions for Use. The QuickDraw venous cannula is substantially equivalent to the predicate QuickDraw venous cannula as the device has the same intended use, indications for use, patient population, fundamental scientific technology, operating principle, and performance specifications.
Functional/Safety Testing:	Functional and safety testing were not applicable for this changed device as the change is only adding a contraindication and warning to the Instructions for Use.
Conclusion:	The QuickDraw Venous Cannula is substantially equivalent to the named predicate device based on technological comparison, principle of

	operation, indications for use, and intended use. There are no new questions of safety and effectiveness.