March 9, 2020

Edwards Lifesciences LLC
Vilma Arechiga
Senior Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K200258
Trade/Device Name: Edwards eSheath Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 31, 2020
Received: February 3, 2020

Dear Ms. Arechiga:

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,

Jaime Raben, Ph.D.
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)*
K200258

Device Name
Edwards eSheath Introducer Set

Indications for Use *(Describe)*
The Edwards eSheath Introducer Set is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 and the SAPIEN 3 Ultra transcatheter heart valves.

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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K200258 510(K) Summary

Submitter: Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92663

Contact: Vilma Arechiga Phone: 949-250-3903, Fax: 949-809-7760

Prepared: January 31, 2020

Trade Name: Edwards eSheath Introducer Set

Common Name: Catheter, Introducer

Classification: Catheter Introducer
21 CFR 870.1340, Product Code DYB

Predicate Devices: Edwards eSheath Introducer Sheath Set (K152225)
Edwards eSheath Introducer Sheath Set (K162184)

Device Description:

The Edwards eSheath Introducer Set contains two dilators and a sheath with hydrophilic coating, and loader packaged with an Edwards delivery system.

It is available with inner sheath diameters of 14 French (model 914ES) and 16 French (model 916ES).

Intended Use:
Entry of interventional devices into the vascular system.

Indication:
The Edwards eSheath Introducer Set is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 and the SAPIEN 3 Ultra transcatheter heart valves.

Comparison to Predicate:
The Edwards eSheath Introducer Set (models 914ES and 916ES) is substantially equivalent to the previously 510(k) cleared predicate because they are the same device with the same intended use, only the specific indication has changed to include SAPIEN 3 Ultra, which is already an approved indication for eSheath under the PMA (P140031/S088 and S091).

There is no change to the patient population, warnings, precautions, or contraindications. There are no changes to the eSheath design or manufacturing specifications.

Summary of Non-Clinical Testing:
Performance Testing for the Edwards eSheath Introducer Set (model 914ES and 916ES) was previously provided in Section 14 of 510(k) K152225 (submitted 8/7/2015, approved 11/24/2015) and K162184 (submitted 8/4/2016, approved 9/2/2016) remains applicable to the expanded indication.

Performance Testing for the Edwards eSheath Introducer Set (model 914ES and 916ES) indication expansion was previously provided in the FDA PMA140031/S088 (submitted 5/24/2019, approved 6/4/2019) and PMA140031/S091 (submitted 7/19/2019, approved 8/21/2019); all results were acceptable.

Specifically, the following design verification and design validation testing was successfully completed:

- Visual Inspection
- Dimensional Inspection
- Radiopacity/Visualization
- Guidewire Compatibility
- Hemostasis
- Lubricity and Durability of the Sheath
- Kink Resistance
- Seam Return After Expansion
- Bond Strength
- Device Interaction
- Hydrophilic Coating Characterization
- USP Particulate Test
- Loader Peel Test
- Material Verification
- Sterilization Validation
- Biocompatibility Tests:
    - Cytotoxicity
    - Hemocompatibility
    - Systemic Toxicity
    - Material Mediated Pyrogenicity
    - Irritation/Intracutaneous Reactivity
    - Sensitization
    - Chemical Acceptability
- Thrombogenicity
- Packaging Integrity
- Shelf Life Verification
- USP Physico-Chemical Test for Plastic Closures

Conclusion:
Based upon device testing and descriptive characteristics, the Edwards eSheath Introducer Set is substantially equivalent to the predicate device and performance testing has demonstrated that safety and efficacy are not adversely impacted. The predicate devices are the same device with the same intended use.