March 27, 2025

Edwards Lifesciences
Andrea Gasca
Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K244046
Trade/Device Name: Edwards eSheath Optima introducer set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 20, 2024
Received: December 30, 2024

Dear Andrea Gasca:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2025.03.27 09:17:47 -04'00'

Finn Donaldson
Acting Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K244046

Device Name
Edwards eSheath Optima introducer set

Indications for Use *(Describe)*
The Edwards eSheath Optima introducer set is indicated for the introduction and removal of compatible devices used with Edwards 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.

510(k) Summary

Submitter: Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
(949) 250-2500

Contact: Andrea Gasca Phone: (949) 250-2500

Prepared: December 30, 2024

Trade Name: Edwards eSheath Optima Introducer Set

Common Name: Catheter, Introducer

Classification: Catheter, Introducer
21 CFR 870.1340, Product Code DYB

Predicate Device: Edwards eSheath Introducer Set (K200258)

Device Description:

The Edwards eSheath Optima introducer set consists of a sheath, vessel dilator, introducer, and in-sheath dilator. The Edwards Optima introducer set is available with inner sheath diameter of 14 French (model 14000ES14). The Edwards eSheath Optima introducer set is used to facilitate introduction of the Edwards transcatheter heart valve systems into the vasculature.

The sheath shaft is composed of two layers; as devices are passed through the sheath, the inner member expands by sliding against itself while the outer jacket expands by stretching radially, temporarily expanding the shaft diameter. A radiopaque marker on the distal end indicates the location of the sheath tip in the body and a hydrophilic coating on the sheath tubing exterior facilitates introduction into the vessel. The sheath tubing mates with a housing, which holds three seals to provide hemostasis, and an extension tube with stopcock for flushing.

The vessel dilator is used to dilate the vessel prior to sheath insertion. The introducer is inserted into the sheath hub and locked prior to insertion into the body over a guidewire. The in-sheath dilator is used to expand the sheath during device use at the physician's discretion. The introducer, vessel dilator, and in-sheath dilator are radiopaque to improve fluoroscopic visibility intra-procedure.

The loader (included in the Edwards delivery system) features a disc valve within the loader cap assembly to help maintain hemostasis, and a scored perforation on the loader tube allowing the loader tubing to be "peeled away" and removed to utilize the full working length of the inserted device.

Intended Use:

Entry of interventional devices into the vascular system.

Indications for Use:

The Edwards eSheath Optima introducer set is indicated for the introduction and removal of compatible devices used with Edwards transcatheter heart valves.

Comparison to Predicate:

The Edwards eSheath Optima introducer set (model 14000ES14) is substantially equivalent to the previously cleared predicate device because the devices have the same intended use and the same or similar technological characteristics. The Edwards eSheath Optima introducer set has modified shaft dimensions, an elastomeric outer jacket for seamless expansion, a locking mechanism for the introducer, and an optional in-sheath dilator. The provided bench testing demonstrates that after the technological changes from the predicate device, the devices remain substantially equivalent.

Summary of Non-Clinical Testing:

Non-clinical testing was completed to demonstrate that the performance characteristics of the Edwards eSheath Optima introducer set are equivalent to the predicate and all design requirements were met. The following bench testing was successfully completed:

- Recovered Outer Diameter (OD)
- In-Sheath Dilator (ISD) Max Distal OD
- Tip OD
- ISD Insertion
- ISD Retrieval
- Tip Inner Diameter (ID)
- Sheath Insertion
- Sheath Retrieval
- Sheath Working Length
- ISD Working Length
- Hemostasis
- Kink Radius
- Fishmouth
- Lubricity and Durability
- Sheath Housing to Shaft Bond Tensile Strength
- Sheath Shaft to Tip Tensile Strength
- Flush Tube to Housing Bond Tensile Strength
- Stopcock to Flush Tub Bond Tensile Strength
- ISD Hub to Shaft Tensile Strength
- Transcatheter Heart Valve (THV)/Sheath Interaction
- Device Interaction
- Guidewire Compatibility
- Delivery System Insertion
- Delivery System Retrieval
- Crimped THV Retrieval
- Radiopacity
- Particulate Testing
- Sterilization Validation
- Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation
    - Material Mediated Pyrogenicity
    - Acute Systemic Toxicity
    - Hemocompatibility
- Thrombogenicity

Conclusion:

Based upon device testing and descriptive characteristics, the Edwards eSheath Optima introducer set is substantially equivalent to the predicate device. The subject device has the same intended use as the predicate device.