



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

November 24, 2015

Edwards Lifesciences  
Karen Reynolds  
Regulatory Affairs Associate III  
1 Edwards Way  
Irvine, California 92614-5686

Re: K152225

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: October 26, 2015  
Received: October 27, 2015

Dear Karen Reynolds:

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 contact the Division of Industry and Consumer Education 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>. 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 <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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for  
Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152225

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 Transcatheter Heart Valve.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(K) Summary

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

**Contact:** Karen Reynolds Phone: 949-250-2500, Fax: 949-756-4408

**Prepared:** August 5, 2015

**Trade Name:** Edwards eSheath Introducer Set

**Common Name:** Catheter, Introducer

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

**Predicate** RetroFlex 3 Introducer Sheath Set (K093877)  
**Devices:** Solopath Balloon Expandable Transfemoral Introducer (K100819)

### Device Description:

The Edwards eSheath Introducer Set consists of a sheath and 2 introducers. It is available with inner sheath diameters of 14 French (model 914ES) and 16 French (model 916ES). The 14 French introducer set is used to facilitate introduction of the 23mm and 26mm SAPIEN 3 THV and Commander Delivery System into the vasculature, and the 16 French introducer set is used to facilitate introduction of the 29mm SAPIEN 3 THV and Commander Delivery System into the vasculature.

The sheath shaft is comprised of 2 layers of material (HDPE/TecoFlex coextruded outer layer and PTFE liner). The outer and inner layer are folded, creating a seam which allows the distal region of the sheath to temporarily expand in diameter when a device is inserted. A tapered strain relief at the proximal end of the sheath shaft helps provide hemostasis when the sheath is inserted.

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 (valves) to provide hemostasis: a duckbill seal, a disc seal, and a cross slit seal. The housing also includes flushport tubing and a stopcock to allow for flushing of the sheath.

Two introducers are provided to aid in the introduction of the sheath into the target vessel, and can also be used for dilation of the vessel prior to sheath insertion. The introducers are radiopaque and feature a tapered tip and guidewire lumen.

### 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 Transcatheter Heart Valve.

**Comparison to Predicate:**

The Edwards eSheath Introducer Set (models 914ES and 916ES) is substantially equivalent in function, performance, and design to the RetroFlex 3 Introducer Sheath Set (K093877), Solopath Balloon Expandable Transfemoral Introducer (K100819), and Cook Medical Check-Flo Performer Extra Large Introducer (K142829). The Edwards eSheath and the Solopath Introducer have an expandable shaft. The Edwards eSheath is expanded in the vasculature by the device that is passed through the inner diameter and the Solopath Introducer is expanded in the vasculature via inflation. The eSheath device compatibility testing was completed using the Edwards SAPIEN 3 Transcatheter Heart Valve and Commander delivery system (commercially available per PMA P140031). The RetroFlex 3 Introducer Sheath Set (K093877) has the same proximal end (housing, hemostasis control, and flush tube) and introducer as the Edwards eSheath but does not include the expansion feature.

**Summary of Non-Clinical Testing:**

Non-clinical testing was completed to demonstrate that the performance characteristics of the Edwards eSheath Introducer Set are equivalent to the predicates, and to verify that design requirements are satisfied. Specifically, the following design verification and validation testing was successfully completed:

- Visual Surface 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
- Sterilization Validation
- Biocompatibility Tests:
  - Cytotoxicity
  - Hemocompatibility
  - Systemic Toxicity
  - Material Mediated Pyrogenicity
  - Irritation/Intracutaneous Reactivity
  - Sensitization
  - Chemical Acceptability
- Thrombogenicity
- Packaging Integrity
- Shelf Life Verification

**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.