DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 2, 2016

Edwards Lifesciences LLC
Yi Gao
Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K162184
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: August 3, 2016
Received: August 4, 2016

Dear Yi Gao:

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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162184

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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K162184 510(K) Summary

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

Contact: Yi Gao
Phone: 949-250-2500
Fax: 949-756-4408

Prepared: August 30, 2016

Trade Name: Edwards eSheath Introducer Set

Common Name: Catheter, Introducer

Classification: Catheter Introducer
21 CFR 870.1340, Product Code DYB

Predicate Device: Edwards eSheath Introducer Set (K152225)

Device Description:

The Edwards eSheath Introducer Set consists of a sheath and two dilators packaged together, and one loader packaged with the Commander delivery system. The Edwards eSheath Introducer Set is available in two sizes: model 914ES (14F inner diameter) and model 916ES (16F inner diameter). The 14F eSheath introducer set is used to facilitate introduction of the 20mm, 23mm and 26mm SAPIEN 3 THV and Commander Delivery System into the vasculature, and the 16F eSheath 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. The sheath shaft exterior includes a hydrophilic coating to facilitate introduction into the target vessel. The distal end of the shaft features a radiopaque marker, and the shaft mates proximally with a housing that contains three valves (seals) to provide hemostasis, an extension tube for flushing, and suture holes on the exterior.

Two dilators 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 dilators are radiopaque and feature a tapered tip and guidewire lumen.

The loader 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

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:

A table comparing the proposed device to the predicate devices is provided below.

	Predicate Device	Subject Device
	Edwards eSheath Introducer Set	**Edwards eSheath Introducer Set (with Loader)**
Manufacturer	Edwards Lifesciences	Identical
510(k)	K152225	K162184
Device Classification	Class II, DYB (21 CFR 870.1340) Catheter Introducer	Identical
Intended Use	Entry of interventional devices into the vascular system	Identical
Indication for Use	The Edwards eSheath Introducer Set is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Transcatheter Heart Valve.	Identical
Target Population	Patients requiring vascular intervention with the SAPIEN 3 Transcatheter Heart Valve	Identical
Anatomical Sites	Human vasculature	Identical
Model Numbers	914ES, 916ES	Identical
Sizes available (French)	14F, 16F inner diameter	Identical
Package Contents	1- Sheath 2- Introducer (dilator)	1 – Sheath 2 – Dilators
		1 – Loader (packaged with the Commander delivery system)
Working Length	36.5 cm	Identical
Guidewire Compatibility	0.035” guidewire	Identical
Radiopaque elements	Sheath, Dilators	Identical
Sheath Hemostasis Control	3 hemostasis seals	Identical
Expansion Mechanism	Expandable seam	Identical
Hydrophilic coating	Sheath, Dilators	Identical
Sterilization Method / Re-use	Ethylene Oxide Single use only	Identical
Sterility Assurance Level	10^{-6} or better	Identical

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:

- Loader Peel Test
- Bond Strength Test
- Biocompatibility Tests:
  - Cytotoxicity
  - Sensitization
  - Irritation/Intracutaneous Toxicity
  - Systemic Toxicity
  - Hemocompatibility
  - Material Verification
  - USP Physico-Chemical Test for Plastic Closures
- Sterilization Validation
- 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.