September 6, 2024

East End Medical I, LLC
Carlos Cruz
QA/RA Director
10320 USA Today Way
Miramar, Florida 33025

Re: K240600
Trade/Device Name: SafeCross Vascular Introducer System (4001)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 22, 2024
Received: March 4, 2024

Dear Carlos Cruz:

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,

Kalkidan Molla -S

Kalkidan A. Molla, MS
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240600

Device Name
SafeCross Vascular System is a Steerable Balloon Introducer System with Access Dilator

Indications for Use *(Describe)*
The SafeCross Vascular System is a Steerable Balloon Introducer System with Access Dilator used for introducing various cardiovascular catheters into the vasculature including the heart. In addition, the device can be used for monitoring intracardiac pressures, sampling blood, and infusing solutions.

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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K240600

510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

East End Medical I LLC
10320 USA Today Way
Miramar, FL 33025

1.2 Official Correspondent

David Joseph Neugaard
10320 USA Today Way
Miramar, FL 33025
+1 (954) 507-7887

1.3 Date of Preparation

September 5, 2024

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

SafeCross Vascular Introducer System

2.1.2 Common/Usual Name

Introducer Catheter
Septostomy Catheter

2.1.3 Classification Information

Classification Name:	Introducer Catheter
Classification Regulation:	21 CFR§870.1340
Class:	2
Product Code:	DYB, Introducer, Catheter
Panel:	Cardiovascular

3. PREDICATE DEVICES

Predicates: SafeCross Transseptal Puncture Device and Introducer (TSP/I) System, K203459. The predicate has not been the subject to a design-related recall.

References: Oscor Destino™ Reach Steerable Sheath, K151951

4. DESCRIPTION OF THE DEVICE

The SafeCross Vascular Introducer System is used to introduce various cardiovascular catheters into the vasculature including the heart. Unlike the predicate device, it does not include an RF Puncture Member and is not intended to cross the atrial septum. The subject device system includes three (3) components: the Steerable Introducer Sheath (SIS), a Long Access Dilator (LAD), and a Short Access Dilator (SAD). In the subject device, the SIS and

LAD are identical to their respective corresponding components of the predicate device (K203459). The Vascular SIS features a compliant, specially shaped, atraumatic overhanging Positioning Balloon on its distal end to facilitate the accurate positioning and stability of the SIS while navigating the patient's vasculature. The physician is able to bi-directionally deflect the distal segment in a range of 0° to 180°. The subject device includes a new component, the SAD (12 Fr, 20 cm in length).

5. INTENDED USE

The SafeCross™ Vascular System is a Steerable Balloon Introducer System with Access Dilator used for introducing various cardiovascular catheters into the vasculature including the heart. In addition, the device can be used for monitoring intracardiac pressures, sampling blood, and infusing solutions.

6. INTENDED USE COMPARED TO THE PREDICATES

The SafeCross Vascular Introducer System has an intended use statement that is a subset of the intended uses from the Predicate. The devices also share the same target patient population, the same users and conditions of use (**Table 1**).

Table 1. Intended Use / Indications for Use Comparison

	Subject Device SafeCross Vascular Introducer System East End Medical I Inc.	**Predicate SafeCross Transseptal Puncture Device and Introducer (TSP/I) System, K203459**	**Same or Different**
Intended Use Statement	The SafeCross™ Vascular System is a Steerable Balloon Introducer System with Access Dilator used for introducing various cardiovascular catheters into the vasculature including the heart. In addition, the device can be used for monitoring intracardiac pressures, sampling blood, and infusing solutions. It is intended for use in general vascular access without requiring transseptal puncture.	The SafeCross Transseptal Puncture Device and Introducer (TSP/I) System is used to introduce various cardiovascular catheters to the heart, including the left side of the heart. The system enables left heart access through a puncture of the atrial septum during a transseptal catheterization procedure. In addition, the device can be used for monitoring intracardiac pressures, sampling blood, and infusing solutions	**Different** (Expanded indication for general vascular access).
Comparison to Reference Device	The Subject Device's intended use aligns with the Oscor Destino™ Reach Steerable Sheath (K151951) Reference Device, which is used for introducing diagnostic and therapeutic devices into the human vasculature, including intracardiac, renal, or other peripheral placements, but not neural placements.	N/A	**Similar** (The use of the Subject Device in general vascular access aligns with the intended use of the Reference Device.)

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATES

A comparison of the technological features between the subject device and the Predicate is shown in **Table 2** below for the Steerable Introducer Catheter.

Table 2. SafeCross Vascular Introducer System Comparison to Predicate

	Predicate Device – Steerable Introducer Sheath SafeCross TSP/I System K203459 East End Medical I Inc.	**Reference Device – Oscor Destino™ Reach Steerable Sheath (K151951)**	**Subject Device – SafeCross Vascular Introducer System East End Medical I Inc.**	**Comparison of Subject Device to Predicate or Reference**
Deflectable Distal Segment Length	S: 5.5 mm M: 6.6 mm L: 9.5 mm	S: 1.7 cm M: 2.2 cm L: 5.0 cm	S: 5.5 mm	Similar, subset
Materials	Biocompatible materials	Biocompatible materials	Biocompatible materials	Same
Radiopacity	Shaft is radiopaque Positioning balloon is inflated with 1 cc of 20% contrast – 80% saline through the Positioning Balloon Inflation Port	Radiopaque distal tip	Shaft is radiopaque Positioning balloon is inflated with 1 cc of 20% contrast – 80% saline through the Positioning Balloon Inflation Port	Same
Proximal end	Hemostasis valve and 2 side ports with 3-way stopcock for Positioning Balloon Inflation Port and Flushing Line Port (injection /aspiration of fluids)	Hemostasis valve and a side port with 3-way stopcock for injection or aspiration of fluids	Hemostasis valve and 2 side ports with 3-way stopcock for Positioning Balloon Inflation Port and Flushing Line Port (injection /aspiration of fluids)	Same
Distal end/tip	Inflatable positioning balloon at the distal tip to facilitate positioning at the fossa ovalis and stabilize the introducer system for precise use of the RF Puncture Member	No balloon	Inflatable positioning balloon at the distal tip to facilitate positioning and stability of the Steerable Introducer Sheath assembly within the vasculature.	Similar, appropriate for indication
OD	0.160”	0.157”, 0.185” or 0.208”	0.160”	Same
ID	8.5F compatible	8.5F, 10F or 12F	8.5F compatible	Same
Sheath effective length	75 cm	67 to 77 cm	75 cm	Same
Compatible guidewire	0.035”	0.035”	0.035”	Same
Distal curve(s)	Min 0° - Max 180° [1]	bi-deflection distal tip	Min 0° - Max 180° [1]	Same

	Predicate Device – Steerable Introducer Sheath **SafeCross TSP/I System K203459** **East End Medical I Inc.**	**Reference Device – Oscor Destino™ Reach Steerable Sheath (K151951)**	**Subject Device – SafeCross Vascular Introducer System** **East End Medical I Inc.**	**Comparison of Subject Device to Predicate or Reference**
Access Dilator	103 cm TSP/I AD provided with kit; compatible with 0.035" guidewire	85 cm to 94cm The dilator has a tapered distal tip	LAD Length: 103cm SAD Length: 20cm Both provided with kit; compatible with 0.035″ guidewire	Similar, addition of the small access dilator
RF Puncture Member	RF Puncture Member: Working length: 103 cm, provided with kit; compatible with 0.035" guidewire	Not Included	Not Included	**Different:** Subject device does not include RF Puncture member in the kit, the Vascular system consists of three components co-packaged in a product kit. 1. Vascular Device 2. Long Access Dilator (LAD) 3. Short Access Dilator (SAD)
Endovascular Navigation Path	Venous: From femoral vein to inferior vena cava to right atrium (to left atrium).	Venous: From femoral vein to inferior vena cava to right atrium. Arterial: From femoral artery to abdominal aorta bifurcation to either thoracic aorta or distally to contralateral femoral/popliteal artery.	Venous: From femoral vein to inferior vena cava to right atrium. Arterial: From femoral artery to abdominal aorta bifurcation to either thoracic aorta or distally to contralateral femoral/popliteal artery.	Same Similar[2]

[1] *Per bench deflection angle testing.*

[2] *Venous vasculature navigation from the groin (femoral vein) up to the right atrium is similar for the 3 devices. Arterial vascular navigation is the same between Reference Device and Subject device and similar between the Predicate and Subject device in terms of complexity, tortuosity and placement.*

Table 3. Component Materials (AD)

	(LAD) Access Dilator (8.5 Fr x 103 cm) East End Medical I Inc.	(SAD) Access Dilator (12 Fr x 20 cm) East End Medical I Inc.	Same or Different
Access Dilator	Shaft, Pebax, barium	Shaft, Polypropylene	**Different:** The SAD was subjected to a series of biocompatibility tests in accordance with FDA guidance, using International Standard ISO 10993-1. • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Hemocompatibility (Hemolysis, Complement Activation, Partial Thromboplastin Time, In Vivo Thrombogenicity, Heparinized Blood Platelet and Leukocyte Count Assay) • Material Mediated Pyrogenicity Results: The test Article (SAD) meet all the test specifications.
	Hub, Polycarbonate	Hub, High Density Polyethylene	

7.1 Similarities and Differences in Technology Comparison

The SafeCross Vascular Introducer System is similar to the SafeCross TSP/I System (K203459) in terms of components and operational use. As outlined in detail in Tables 1-3, technological differences compared to the predicate SafeCross TSP/I System include that the subject SafeCross Vascular Introducer System contains an SAD, does not include an RF puncture member, and incorporates two modifications to the indication for use: (1) removal of transseptal crossing to the left heart and (2) inclusion of peripheral vasculature. While these modifications do not alter the intended use of the device, the subject device's inclusion of general vasculature to the indication necessitated a risk assessment using a reference device (Oscor Destino Reach Steerable Sheath - K151951) to help address safety and effectiveness of the new technological characteristics. A detailed assessment of anatomical navigation paths used for both the reference and subject device led to an SIS deflection angle testing ("distal curve(s)" in Table 2) specification change from 90° to 149.6°. There have been no changes to manufacturing or sterilization of the device. While the packaging materials remain unchanged, the configuration differs between the subject and predicate devices. The subject device, SafeCross Vascular Introducer System, includes both a Long Access Dilator (LAD) and a Short Access Dilator (SAD), whereas the predicate device is co-packaged with a single LAD and an RF puncture member.

The technology of the Subject Steerable Introducer Sheath is identical to the Predicate Introducer Sheaths. Both the SafeCross Steerable Introducer Sheath and the Predicate are co-packaged with an access dilator. The technology of the Long Access Dilator (LAD) is identical between the predicate and subject devices.

8. Performance Testing

Design Verification and Validation testing that was conducted on the predicate device was leveraged to support the subject device, due to a risk-based assessment of the similarity or equivalence in geometry and functionality of the device components.

While no new design verification or validation testing was performed on the subject

device, in using technical information from the reference device (K151951), a new specification for the SIS deflection angle (149.6°) was retroactively applied to predicate device prior SIS deflection testing to ensure the subject device can be curved to navigate through all potential navigation pathways. Testing was not repeated, as the predicate and subject device have an identical SIS component that met the 149.6° specification.

Additionally, biocompatibility testing was conducted on the newly proposed short access dilator (SAD) for the subject device to provide evidence that the new technological characteristic (i.e., new material of the SAD) does not raise different questions of safety and effectiveness compared to the predicate.

The SAD was subjected to a series of biocompatibility tests in accordance with FDA guidance, using International Standard ISO 10993-1.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility (Hemolysis, Complement Activation, Partial Thromboplastin Time, in vivo thrombogenicity, Heparinized Blood Platelet and Leukocyte Count Assay)
- Material Mediated Pyrogenicity

9. Conclusions

The SafeCross Vascular Introducer System has the same intended use as the SafeCross TSP/I System predicate device, and similar technological characteristics. The differences in technological characteristics (i.e., new material of the SAD) do not raise new or different questions of safety and effectiveness since all biocompatibility testing conducted meet the specifications. The Oscor Destino™ Reach Device was used as a reference device for some of the performance evaluations. Therefore, the SafeCross Vascular Introducer System is substantially equivalent to the predicate device.