July 6, 2021

East End Medical I LLC
% Diane Horwitz
Owner
Mandell Horwitz Consultants LLC
5 Lake Como Ct.
Greenville, South Carolina 29609

Re: K203459
Trade/Device Name: SafeCross Transseptal Puncture and Introducer (TSP/I) System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB, DXF
Dated: June 7, 2021
Received: June 8, 2021

Dear Diane Horwitz:

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,

Rachel Neubrander
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)*

K203459

Device Name

SafeCross Transseptal Puncture and Introducer (TSP/I) System

Indications for Use *(Describe)*

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.

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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510(k) SUMMARY

1. GENERAL INFORMATION

K203459

1.1 Submitter and 510(k) Owner

East End Medical I LLC
1157 Sawgrass Corporate Parkway
Sunrise, FL 33323

1.2 Official Correspondent

Diane Horwitz, Ph.D.
5 Lake Como Ct.
Greenville, SC 29609

1.3 Date of Preparation

July 1, 2021

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

SafeCross Transseptal Puncture and Introducer (TSP/I) 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

Classification Name:	Septostomy Catheter
Classification Regulation:	21 CFR §870.5175
Class:	2
Product Code:	DXF, Catheter, Septostomy
Panel:	Cardiovascular

3. PREDICATE DEVICES

Primary Predicate Device: Agilis NXT Steerable Introducer, K081645, St. Jude Medical

Secondary Predicate Device: NRG Transseptal Needle, K073326, Baylis Medical Company, Inc.

Reference Device: AcQGuide Flex with AcQCross QX, AcQGuide Mini with AcQCross QX, K193509, Acutus Medical

4. DESCRIPTION OF THE DEVICE

The SafeCross Transseptal Puncture and Introducer (TSP/I) System is used to access the heart left atrium through a puncture of the atrial septum. The System includes three (3) components: the Steerable Introducer Sheath, the RF Puncture Member, and an Access Dilator. The Steerable Introducer Sheath has a compliant balloon at the tip for protection of the septum, and the RF Puncture member is compatible with five (5) of the most common electrosurgical generators.

5. INTENDED USE

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.

6. INTENDED USE COMPARED TO THE PREDICATES

The TSP/I System has an intended use statement that is comprised of a combination of the intended uses from both Predicates. The statement is similar with the exception of several word changes specific to the subject device. 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 TSP/I System East End Medical I Inc.	**Primary Predicate Agilis NXT Steerable Introducer St. Jude Medical K081645**	**Secondary Predicate NRG Transseptal Needle Baylis Medical Company, Inc. K073326**
Intended Use Statement	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.	The Agilis ™ NXT Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	Creation of an atrial septal defect in the heart. Secondary applications include transseptal heart access, monitoring intracardiac pressures, sampling blood, and infusing solutions.

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATES

A comparison of the technological features between the TSP/I System and the Predicates is shown in **Table 2** below for the Steerable Introducer Catheter and in **Table 3** for the RF Puncture Member.

Table 2. TSP/I Steerable Introducer Sheath and Access Dilator Technology Comparison to Predicates

	Subject Device – Steerable Introducer Sheath SafeCross TSP/I System East End Medical I Inc.	**Primary Predicate Agilis NXT Steerable Introducer St. Jude Medical K081645 (L Curve)**	**Same or Different**
Deflectable Distal Segment Length	S: 5.5 mm M: 6.6 mm L: 9.5 mm	K081645 L: 8.4 mm	Same
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	"The sheath is filled with radiopaque material for visualization under fluoroscopy"	Similar. Visibility under fluoroscopy was confirmed with bench and usability testing
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	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	Different. Use of an atraumatic compliant balloon is common in cardiovascular procedures. Bench testing and use validation study confirm requirements and specifications were met. This change does not raise new issues of safety or effectiveness
OD	0.160"	0.161"	Similar
ID	8.5F compatible	8.5F compatible	Same
Sheath effective length	75 cm	71 cm	Similar
Compatible guidewire	0.035"	0.032"	Similar
Distal curve(s)	> 90° bidirectional	> 90° bidirectional	Same
Access Dilator	103 cm TSP/I AD provided with kit; compatible with 0.035" guidewire	94 cm AD provided with kit; compatible with 0.032" guidewire	Same

Table 3. TSP/I RF Puncture Member Technology Comparison to Predicate

	Subject Device – RF Puncture Member SafeCross TSP/I System East End Medical I Inc.	**Secondary Predicate NRG TRANSSEPTAL NEEDLE Baylis Medical Company, Inc. K073326**	**Same or Different**
Working length	103 cm	98 cm	Similar
Outer shaft diameter	0.110" (8.5F)	0.053" and requires 8.5F dilator for use	Same
Visibility under fluoroscopy	Visible due to metal material	Visible due to metal material	Same
Compatible guidewire	0.035"	0.032"	Similar
Compatible Generator	Third-party FDA-cleared electrosurgical generators: • Bovie OR/PRO 300 • CONMED System 5000 • ERBE VIO 300D • Ethicon / Megadyne Mega Power • Medtronic/ Covidien/ Valleylab Force FX/FX-C	The companion generator is cleared by the Baylis Medical Company, Inc., Models RFP-100 and RFP-100A	Different. The Predicate device is used with one generator from the same manufacturer, while the Subject device may be used with several qualified generators. All generators are set to 50 W Power; Subject device details the generator settings in IFU and in training. A Reference Device was selected, AcQGuide Flex (Acutus Medical, Inc., K193509) as it is similarly cleared for use with an electrosurgical generator from a Third Party manufacturer (which is the same as the Subject device compatible generator).
Mode	Monopolar mode, CUT modality, 50 W	Up to 50W (RFP-100A Generator)	Each compatible generator has been tested with the Subject device and been characterized to have equivalent electrical performance with the Predicate device.
Connector	Bovie D-shape 4mm connector	Proprietary connector	Similar

7.1 Similarities and Differences in Technology Comparison

The SafeCross TSP/I System is equivalent to the combination of the Agilis NXT Steerable Introducer (K081645) and the NRG Transseptal Needle (K073326) in terms of components and operational use.

The technology of the Subject Steerable Introducer Sheath is identical to the Predicate Introducer Sheaths with the exception that the Subject device includes a Positioning Balloon on its distal end. Both the SafeCross Steerable Introducer Sheath and the Predicate are co-packaged with an access dilator.

The technology of the SafeCross RF Puncture Member is almost identical to the Predicate Puncture Member. Both devices use RF energy technology to cross the septal wall, using an electrosurgical generator. Both devices are radiopaque for visualization during the procedure using fluoroscopy. Both devices utilize similar output powers from similar electrosurgical generators. The SafeCross RF Puncture Member has the advantage of being compatible with the most common electrosurgical generators. Electrical safety and compatibility have been demonstrated.

8. PERFORMANCE TESTING

A series of bench tests was performed to demonstrate that the TSP/I System meets its performance specifications using final finished, sterilized and preconditioned product. Comprehensive verification and validation activities were successfully completed, raising no new issues of safety or effectiveness. All testing passed the acceptance criteria.

Performance testing was conducted against known standards and product specifications and evaluated the following:

Performance and Physical Requirements of the TSP/I System

- Validation testing to demonstrate compatibility with accessory devices and radiopacity
- Dimensional verification
- Deliverability and retraction
- Structural integrity (leakage, joint strength, flexibility, torque strength)
- Particulate testing
- Usability validation testing

Performance and Physical Requirements of the TSP/I Steerable Introducer Sheath

- Balloon dimensional and performance characteristics, deployment and retraction
- Flow and pressure testing

Performance and Physical Requirements of the TSP/I RF Puncture Member

- Electrical verification and compatibility according to IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2
- Arc integrity verification
- Coring test

Biological Safety Testing
The TSP/I System 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, Thromboresistance)
- Material Mediated Pyrogenicity

Sterilization

Sterilization and sterilization validation were performed to ensure a SAL of 10^{-6}, according to international sterilization standards.

Packaging Validation and Shelf Life

Visual Inspection, Bubble Leak and Seal Strength testing was used to evaluate integrity of the packaging configuration. Testing was conducted after sterilization, environmental conditioning including aging, and simulated shipping and distribution.

The results of the performance testing conclude the SafeCross TSP/I System is safe and is substantially equivalent to the predicate devices.

9. CONCLUSIONS

The information presented in this 510(k) submission demonstrates that the East End Medical I LLC SafeCross TSP/I System is substantially equivalent to the predicate devices.