September 28, 2018

Transseptal Solutions Ltd.
℅ Mary LeGraw
Consultant to Transseptal Solutions
Boston Biomedical Associates
100 Crowley Drive, Suite 216
Marlborough, Massachusetts 01752

Re: K181088
Trade/Device Name: TSP Crosser Transseptal Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 23, 2018
Received: August 24, 2018

Dear Mary LeGraw:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 E. Neubrander -S

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

Enclosure

5 INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181088

Device Name
TSP CrosserTM Transseptal Access System

Indications for Use *(Describe)*
The TSP Crosser Transseptal Access System is intended to both puncture the interatrial septum during a transseptal catheterization procedure and to introduce various cardiovascular catheters into the left side of the heart.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

6 510(K) SUMMARY

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date is April 4, 2018 [21 CFR 807.92(a)(1)].

6.1 Submitter

Name:	Transseptal Solutions Ltd.
Address:	10 HaGavish St. P.O. Box 4060 Netanya, 4250708 Israel
Phone:	+972 9 8914217
Contact Person:	Mary P. LeGraw Boston Biomedical Associates 100 Crowley Drive, Suite 216 Marlborough, MA 01752 mlegraw@bbacro.com Phone: (508) 691-7038 Fax: (508) 351-8637

6.2 Device

Name of Device:	TSP Crosser™ Transseptal Access System (Model Number TSUS001)
Common Name:	Introducer Catheter
Classification Name:	Catheter, Introducer
Regulatory Class:	Class II
Product Code:	DYB, 21 CFR 870.1340
Device Panel:	Division of Cardiovascular Devices

6.3 Predicate Device

Primary Predicate Name and 510(k) Number:	St. Jude ACross™ Transseptal Access System (K070417)
Reference Device:	St. Jude Agilis™ NxT Steerable Introducer (K081645)

6.4 Device Description

The TSP Crosser System is intended to be used both to puncture the interatrial septum during a transseptal catheterization procedure and to introduce various cardiovascular catheters into the left heart chambers. The main components of the TSP Crosser System are:

- Steerable introducer sheath with handle and radiopaque wire loop that is compatible with catheters up to 8F
- Dilator that is compatible with guidewires up to a maximum diameter of 0.035”
- Transseptal needle with Stylet

The System is provided sterile (EO) and is intended for single use only. The device is designed to provide controlled transseptal access in the cardiac left atrial anatomy. The TSP catheter introducer sheath is an elongated shaft with a central lumen capable of incorporating the needle and stylet assembly, the dilator, as well as allow passage and orientation of operational catheters up to 8F. The introducer incorporates a steerable tip that can be deflected bi-directionally up to 180° with a curvature radius of 22mm. The steerable introducer handle includes a rotating knob that maintains the rotational and longitudinal positioning of the sheath and deflects the sheath’s tip 180° on each side. There is a nitinol loop wire positioned at the distal end of the introducer that is visible under fluoroscopy and provides a visual aid to the user when positioning the needle on the fossa ovalis. The introducer contains a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with a three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring.

The dilator has an outer diameter of 8F and inner diameter of 0.035” and includes a central lumen that facilitates the transseptal needle/stylet in a similar fashion to conventional dilators. The transseptal needle assembly consists of a luminal stainless-steel needle and solid stainless-steel stylet. The needle is used to puncture the interatrial septum during the catheterization procedure and houses a central lumen that accommodates the stylet.

6.5 Indications for Use

The TSP Crosser System is intended to be used both to puncture the interatrial septum during a transseptal catheterization procedure and to introduce various cardiovascular catheters into the left heart chambers.

6.6 Comparison of Technological Characteristics with the Predicate Device

The proposed device is substantially equivalent to the design and materials in the predicate device. The table below summarizes the comparisons between the predicate device and the TSP Crosser System

Table 6-1: Substantial Equivalence

Technical Characteristic	Proposed Device TSP Crosser System (Pending)	Predicate Device ACross System (K070417)	Predicate Device Agilis NxT System (K081645)
Integrated System			
Indications for Use	The TSP Crosser Transseptal Access System is intended to both to puncture the interatrial	The St. Jude Medical ACross Transseptal Access System is used both to puncture	The Agilis NxT Steerable Introducer is indicated for introducing various cardiovascular catheters

Technical Characteristic	Proposed Device TSP Crosser System (Pending)	Predicate Device ACross System (K070417)	Predicate Device Agilis NxT System (K081645)
	septum during a transseptal catheterization procedure and to introduce various cardiovascular catheters into the left side of the heart.	the interatrial septum during a transseptal catheterization procedure and to introduce various cardiovascular catheters into the left side of the heart.	into the heart, including the left side of the heart through the interatrial space.
Regulatory Class	Class II	Class II	Class II
Product Code	DYB	DYB	DYB
Regulation Name	Catheter Introducer	Catheter Introducer	Catheter Introducer
Regulation Number	21 CFR 870.1340	21 CFR 870.1340	21 CFR 870.1340
Common Name	Transseptal Catheter Introducer	Transseptal Catheter Introducer	Transseptal Catheter Introducer
Introducer / Sheath			
Sheath Characteristics	**TSP Crosser Steerable Introducer**	**ACross Swartz™ Guiding Introducer**	**Agilis Steerable Introducer**
Shaft Deflection	Pull Wire	Stable braided (fixed curve)	Pull Wire
Deflection Mechanism	Rotating knob on handle	Not steerable	Rotating knob on handle
Labeled Internal Diameter	8.7F	8F	8.5F
Labeled Outer Diameter	14 F	Unavailable	11.5F
Catheter Compatibility	8F OD or less	8F OD or less	8F OD or less
Shaft Usable Length	68.5cm	63cm and 81cm	61cm, 71cm, 82cm
Maximum Deflection	180° Bi-directional	45°, 60°, 90°, 135°, 180° (Fixed Curves)	90° Clockwise 180° Counter Clockwise Bi-directional
Radiopaque Tip	YES	YES	YES
Hemostasis	Internal valve	Internal valve	Internal valve
Shaft Construction	Laminated, SS braided shaft, inner PTFE liner, deflectable sheath	Braided Sheath	Laminated, SS braided shaft, inner PTFE liner, deflectable sheath
Sheath Primary Materials	Stainless steel and PTFE inner liner, outer Pebax jacket	Unavailable	PE, polycarbonate, ABS, PVC and silicone rubber (IFU)
System Dilator			
Dilator Characteristics	**TSP Crosser Dilator**	**ACross Dilator**	**Agilis Dilator**
Purpose	To provide support to the sheath and ensure smooth advancement into the vessel	To provide support to the sheath and ensure smooth advancement into the vessel	To provide support to the sheath and ensure smooth advancement into the vessel
Outer Diameter	8.5F	8F, 8.5F	8.5F
Guidewire Compatibility	0.035”	0.032”	0.032”
Effective Length	94.9cm	71cm, 89cm	98cm
Tip Length	10.5mm	Unavailable	9mm
Material	High Density Polyethylene (HDPE)	Unavailable	Unavailable
Transseptal Needle / Stylet			

Technical Characteristic	Proposed Device TSP Crosser System (Pending)	Predicate Device ACross System (K070417)	Predicate Device Agilis NxT System (K081645)
Transseptal Needle/Stylet Characteristics	**TSP Crosser Needle**	**TSP Crosser Stylet**	**ACross BRK Transseptal Needle**
Overall Length	105.5 cm	107.8 cm	71cm, 89cm, 98cm
Working Length	100 cm	120.5 cm	Unknown
Internal Diameter	0.6 mm	N/A	Unknown
Outer Diameter	0.9 mm	0.45 mm	1.02 mm
Curve Angle	Straight with flexible tip (passive steering using sheath deflection)	Straight	BRK: Standard curve, 19° angle between curved segment and need shaft BRK-1: Accentuated curve, 53° angle
Material	304 Stainless Steel	304 Stainless Steel	Stainless Steel
System Performance			
Bench Testing Demonstrate Equivalence	YES	YES	YES
Biocompatible	YES	YES	YES
Sterilization	EO	EO	EO

6.7 Performance Data and Substantial Equivalence

The technical characteristics between the subject device and the predicate devices have been evaluated through design, material and dimensional comparison, bench and biocompatibility tests to provide evidence of substantial equivalence. The TSP Crosser Transseptal Access System is substantially equivalent to the predicate devices based on comparison of the devices functionality, compatibility, technological characteristics and indications for use.

In vitro bench testing was performed on the TSP Crosser System to assure reliable design and performance. The non-clinical tests performed include Visual and Dimensional Verification, Steerability, Air Leakage, Liquid Leakage, Pushability, Trackability, Torqueability, Simulated Use, Tensile Strength, and Corrosion.

Biocompatibility testing consisted of Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Pyrogenicity, ASTM Hemolysis (Direct and Indirect), SC5b-9 Complement Activation and *In Vivo* Thrombogenicity.

In vivo animal studies were performed to confirm the safety and performance of the TSP Crosser System in a left heart catheterization and to demonstrate the ability of the System to successfully introduce commercial percutaneous catheters into the left chambers of the heart.

Clinical data was also collected outside the United States that supports the safety and performance of the TSP Crosser System for its labeled indications for use.

6.8 Conclusions

Transseptal Solutions believes the proposed TSP Crosser System is substantially equivalent to the legally marketed predicate devices. The indications for use, methods of operation, design and materials used are either identical or substantially equivalent to existing legally marketed predicate products. In addition, performance testing, in addition to in vivo animal studies and clinical data supports substantial equivalence of the proposed and predicate devices.