February 3, 2022

Thrombolex, Inc.
% Diane Horwitz
Regulatory
Eminence Clinical Research Inc.
5 Lake Como Ct.
Greenville, South Carolina 29609

Re: K192598
Trade/Device Name: Bashir S-B Endovascular Catheter, Ref. No. 7101
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Diane Horwitz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 18, 2019. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2022.02.03 14:30:38 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

October 18, 2019

Thrombolex, Inc.
% Diane Horwitz, PhD
Regulatory Consultant
Eminence Clinical Research, Inc.
5 Lake Como Ct.
Greenville, South Carolina 29609

Re: K192598
Trade/Device Name: Bashir™ S-B Endovascular Catheter, Ref. No. 7101
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: September 19, 2019
Received: September 20, 2019

Dear Dr. 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,

For Eleni Whatley
Digitally signed by Eleni Whatley
Date: 2019.10.18 09:39:55 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192598

Device Name
Bashir™ S-B Endovascular Catheter, Ref. No. 7101

Indications for Use *(Describe)*
The Bashir™ S-B Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

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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THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Thrombolex, Inc.
75 Britain Dr.
New Britain PA 18901

1.2 Official Correspondent

Diane Horwitz, Ph.D.
5 Lake Como Ct.
Greenville, SC 29609
Telephone: 703.307.2921
Email: dhorwitz@ecr-inc.com

1.3 Date of Preparation

October 17, 2019

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

Bashir™ S-B Endovascular Catheter, Ref. No. 7101

2.1.2 Common/Usual Name

Continuous Flush Catheter

2.1.3 Classification Information

Classification Name:	Continuous Flush Catheter
Classification Regulation:	21 CFR 870.1210
Class:	2
Product Code:	KRA – Continuous Flush Catheter
Panel:	Cardiovascular

3. PREDICATE DEVICE

The predicate device is the Bashir™ Endovascular Catheter, Reference No. 7201, K183290.

4. DESCRIPTION OF THE DEVICE

The Bashir™ S-B Endovascular Catheter (Model 7101) is a continuous flush catheter designed to enable delivery of physician-specified fluids, including thrombolytics, into the peripheral circulation. The design of the Bashir™ S-B Endovascular Catheter allows for delivery and positioning of the catheter at the target peripheral location via a sheath, over a guidewire using fluoroscopic guidance. Depending on the target location, the infusion can be initiated either in the non-expanded position (for vessels with smaller diameters), or by controlled expansion of the infusion basket to a desired dimension inside the vessel by the interventional specialist under fluoroscopic guidance. The physician-specified solution is delivered via multiple laser-drilled holes through the infusion limbs of the Bashir™ S-B Endovascular Catheter after placement. After the completion of solution delivery, the infusion limbs are collapsed to a straight position and then the Bashir™ S-B Endovascular Catheter is retracted into the sheath and removed.

The Bashir™ S-B Endovascular Catheter is comprised of common materials used in vascular catheters. The catheter is mechanical and contains no electrical components.

5. INDICATION FOR USE

The Bashir™ S-B Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

6. COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The Bashir™ S-B Endovascular Catheter is intended to be used in the same interventional procedures in the same target population (patients with thrombosis in the peripheral vasculature) and have the same primary function of providing a conduit for infusion of solutions. The Bashir™ S-B Endovascular Catheter has an identical intended use/indications for use statement compared to the predicate device.

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

The Bashir™ S-B Endovascular Catheter is substantially equivalent to the predicate device regarding its similar intended use, fluid infusion function, design, materials, packaging and sterility.

The parent device was modified to shorten the infusion basket from 12.5 cm to 10 cm to facilitate use in different anatomical size and/or locations within the peripheral vasculature to increase efficiency of exposure of the clot to thrombolytic solutions. Features of the handle were changed to improve ergonomics and torque resistance of the connector.

Through product testing, Thrombolex has demonstrated that the technological differences between the subject device and the predicate device do not raise different issues of safety or effectiveness.

8. PERFORMANCE TESTING

This 510(k) notification provides performance data to establish the substantial equivalence of the Bashir™ S-B Endovascular Catheter to the predicate device. The following is a summary of the performance data repeated for the modified device.

Performance Testing - Bench: Performance testing was repeated to confirm that the device modifications did not adversely affect the device performance.

The testing included an evaluation of: Trackability, advancement force, slider actuator force, catheter retraction, radial force, delivery flow rate, infusion pressure at various flow rates, infusion pressure with pulse spray, dimensional verification, joint tensile strengths and label legibility. The performance data demonstrate that the new device is substantially equivalent to the predicate device.

Sterilization and Shelf Life: The devices are sterilized using standard methods and the sterilization cycles have been validated following international standards. The shelf life of the devices was established through stability studies. The sterilization validation complied with ISO 11135: 2014. The sterilization cycle was validated to a sterility assurance level of 10^{-6}. The shelf life of the Bashir Catheters was established through accelerated aging studies, and support a shelf life of 2 years.

Usability Testing*:* Usability testing was performed using the to-be-marketed modified device handle by ten (10) intended users and was found to be meet pre-defined acceptance criteria.

9. CONCLUSIONS

The information presented in this 510(k) submission demonstrates that the Bashir™ Endovascular S-B Catheter is substantially equivalent to the predicate device.