February 3, 2022

Thrombolex, Inc.
% Diane Horwitz
Regulatory Consultant
Eminence Clinical Research Inc.
2995 Steven Martin Dr.
Fairfax, Virginia 22031

Re: K183290
Trade/Device Name: Bashir Endovascular Catheter Model 7201, Bashir N-X Endovascular Catheter, Mode 7200
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 February 25, 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 14:29:43 -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

February 25, 2019

Thrombolex, Inc.
℅ Diane Horwitz
Regulatory Consultant
Eminence Clinical Research Inc.
2995 Steven Martin Dr.
Fairfax, Virginia 22031

Re: K183290
Trade/Device Name: Bashir Endovascular Catheter Model 7201, Bashir N-X Endovascular Catheter Model 7200
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: January 31, 2019
Received: January 31, 2019

Dear Ms. 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/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,

Gregory O'Connell 2019.02.25 16:29:55 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183290

Device Name
Bashir™ Endovascular Catheter Model 7201
Bashir™ N-X Endovascular Catheter Model 7200

Indications for Use *(Describe)*
Bashir™ Endovascular Catheter:

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

Bashir™ N-X Endovascular Catheter:

The Bashir™ N-X Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids into the peripheral and pulmonary artery 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
K183290

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

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

1.2 Official Correspondent

Diane Horwitz, Ph.D., RAC
2995 Steven Martin Dr.
Fairfax, VA 22031
Telephone: 703.307.2921
Email: dhorwitz@ecr-inc.com

1.3 Date of Preparation

February 21, 2019

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

Bashir™ Endovascular Catheter, Model 7201
Bashir™ N-X Endovascular Catheter, Model 7200

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 AND REFERENCE DEVICES

Ekosonic Endovascular System with Rapid Pulse Modulation (cleared under K111705).

Reference Devices are AngioJet Zelante (K151313), Cordis Maxi LD 14 mm PTA Balloon (K963000), and 5 mm balloon catheters [Boston Scientific Sterling PTA Balloon Dilatation Catheter (K132430), Abbott Fox SVA PTA Catheter (K092286), Cordis Savvy Long PTA Balloon (K942094)].

4. DESCRIPTION OF THE DEVICE

Thrombolex developed the Bashir™ Endovascular Catheter (Model 7201) to enable delivery of physician-specified fluids, including thrombolytics, into the peripheral circulation. The Bashir™ N-X Endovascular Catheter (Model 7200) is a second model developed for infusion of physician-specified fluids in the pulmonary artery. The Bashir™ N-X differs from the Bashir™ Endovascular Catheter in that the infusion limbs do not expand into an infusion basket but remain collapsed in a straight configuration. The two device models have a different appearance, namely in the handle design and color, which ensures appropriate use and identification.

The design of the Bashir™ 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 then delivered via multiple laser-drilled holes through the infusion limbs of the Bashir™ Endovascular Catheter. After the completion of solution delivery, the infusion limbs are collapsed to a straight position in the case of peripheral vasculature, and then the Bashir™ Endovascular Catheter is retracted into the sheath and removed.

The handle of the Bashir™ N-X Endovascular Catheter has been modified to disable expansion of the basket. The Bashir™ N-X Endovascular Catheter, unexpanded, is thus similar to other straight infusion catheters including the predicate device.

Delivery of the Bashir N-X™ Endovascular Catheter into the pulmonary artery is accomplished using a long guide sheath using standard interventional techniques. The Bashir™ Endovascular Catheter is placed over a guidewire inside the sheath to the desired location under fluoroscopic guidance. The catheter does not come in direct contact with the right atrium, tricuspid valve, right ventricle or pulmonic valve at any time, as it is within a guide sheath.

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

5. INDICATION FOR USE

The indications for use / intended use statement for the Bashir™ Endovascular Catheter and the Bashir™ N-X Endovascular Catheter are as follows:

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

Bashir™ N-X Endovascular Catheter: The Bashir™ N-X Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids into the peripheral and pulmonary artery vasculature.

6. COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The Bashir™ Endovascular Catheter and the Bashir™ N-X Endovascular Catheter and the predicate device, the Ekosonic Endovascular System, are intended to be used in the same interventional procedures in the same target population (including patients with thrombosis in the vasculature) and have the same primary function of providing a conduit for infusion of solutions. Thus, the Bashir™ Endovascular Catheter and Bashir™ N-X Endovascular Catheter have almost identical intended use / indications for use statements when compared to the predicate device, Ekosonic Endovascular System.

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

The Bashir™ Endovascular Catheter is substantially equivalent to the predicate device regarding its similar intended use, fluid dispersion function, certain aspects of design, materials and sterility.

There are also some differences between the technological characteristics of the Bashir™ Endovascular Catheter, the Bashir™ N-X Endovascular Catheter and the predicate device. These differences do not raise new questions of safety or effectiveness, and there are standard methods and tests that can evaluate the effects of new or different characteristics on safety and performance.

- Infusion limbs at the distal end of the Bashir™ Endovascular Catheter can expand in the peripheral circulation, to facilitate the distribution of infusate in the peripheral vasculature. This is compared to the straight distal end of the predicate catheter. This difference does not raise different questions of safety or effectiveness, since appropriate design verification and validation testing was performed by comparison of the Bashir™ Endovascular Catheter to legally marketed reference devices with expandable features to demonstrate that the radial force exerted is similar for the Bashir™ Endovascular Catheter compared to the balloon reference devices.
- The ultrasound transducers and the electronic and software-controlled components of the predicate device are not present for the subject device.
- The Bashir Catheter and Bashir N-X use the infusion limbs to aid in distribution of fluids. Both models of the Thrombolex device utilize the multiple lumens of the distal infusion region to provide a large surface for infusion of physician-specified fluids and, also to permit flow of native blood containing endogenous thrombolytics through the channel(s) into peripheral the blood vessel or pulmonary artery (Bashir™ N-X Endovascular Catheter).

- The Bashir™ Catheters have the capability for direct blood pressure measurement via the central lumen of the subject devices.

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™ Endovascular Catheter and the Bashir™™ N-X Endovascular Catheter to the predicate device. The following is a summary of the performance data.

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 has been 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 1 year.

Biocompatibility: Biocompatibility evaluation has been performed to show the finished, sterilized device is biocompatible and suitable for its intended use. Both ISO 10993 and FDA Draft Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" have been taken into account to evaluate the biocompatibility of the subject device.

Human Factors Testing*:* Usability testing was performed using the to-be-marketed device and was found to be substantially equivalent for the intended users, uses and use environments. Participants were able to perform procedures with the Bashir™ Endovascular Catheter and the Bashir™ N-X Endovascular Catheter and meet the pre-defined acceptance criteria.

Performance Testing- Bench: Performance testing was performed to characterize the Bashir™ Endovascular Catheter and the Bashir™ N-X Endovascular Catheter in comparison to the predicate device.

The testing included an evaluation of: Kink radius, trackability, advancement force, slider actuator force, catheter retraction, radial force, delivery flow rate, infusion pressure at various flow rates, infusion pressure with pulse spray, pressure measurement through central lumen, guidewire compatibility, dimensional verification, compliance of injection hubs, air leakage, fluid leakage, stress cracking, resistance to separation, torque strength, corrosion resistance, joint tensile strengths and particulate generation. The performance data demonstrate that the new devices are substantially equivalent to the predicate device.

Performance Testing - Animal: The safety of the Bashir™ Endovascular Catheter was demonstrated in a GLP porcine study. Use of the catheter had no adverse effects systemically or pathologically, supporting the safe use of the device.

9. CONCLUSIONS

The information presented in this 510(k) submission demonstrates that the Bashir™ Endovascular Catheter and the Bashir™ N-X Endovascular Catheter are substantially equivalent to the predicate device.