April 20, 2023

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

Re: K222095
Trade/Device Name: BASHIR™ Endovascular Catheter, Ref. No. 7201
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
Dated: March 17, 2023
Received: March 17, 2023

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.04.20 05:44:59 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222095

Device Name
BASHIR™ Endovascular Catheter, Ref. No. 7201
BASHIR™ S-B Endovascular Catheter, Ref. No. 7101

Indications for Use *(Describe)*
The BASHIR™ Endovascular Catheter and BASHIR™ S-B Endovascular Catheter are mechanical thrombolysis catheters indicated for the:

- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism.
- Infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus.

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

April 19, 2023

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

BASHIR™ Endovascular Catheter, Ref. No. 7201
BASHIR™ S-B Endovascular Catheter, Ref. No. 7101

2.1.2 Common/Usual Name

Continuous Flush Catheter

2.1.3 Classification Information

Classification Name:	Mechanical Thrombolysis Catheter
Classification Regulation:	21 CFR 870.5150
Class:	2
Product Code:	QEY, KRA
Panel:	Cardiovascular

3. PREDICATE DEVICE

Ekosonic Endovascular Device, Boston Scientific, K211080

Reference Devices:
BASHIR™ Endovascular Catheter, K211061
BASHIR™ S-B Endovascular Catheter, K192598

4. DESCRIPTION OF THE DEVICE

The BASHIR™ Endovascular Catheter is a device intended for mechanical thrombolysis via expanding the distal infusion basket, allowing localized infusion of physician-specified fluids, including thrombolytics, into the peripheral or pulmonary vasculature. The distal infusion segment of the device is 12.50 cm (4.94 in.) long and consists of an expandable basket with a nitinol core surrounded by mini-infusion catheters, each with multiple infusion holes (hereafter referred to as the "infusion basket"). The infusion basket is expanded and closed using the red actuator located on the handle at the proximal end of the device. The BASHIR™ S-B Endovascular Catheter is a second model intended for smaller anatomies, with an infusion basket that is 10.0 cm (3.94 in.). The devices are otherwise the same.

The physician-specified fluid is then delivered via the basket infusion line located on the handle. Pulse sprays are followed by infusion through laser-drilled holes in the infusion limbs of the basket after placement in the peripheral vasculature or in the pulmonary artery. After the completion of fluid delivery, the infusion limbs are collapsed to a straight position and then the catheter is retracted into the sheath and removed from the patient.

The BASHIR™ Endovascular Catheter and BASHIR™ S-B Endovascular catheters are composed of common biocompatible materials used in vascular catheters. The catheters are mechanical and contain no electrical components and require no capital equipment.

5. INTENDED USE / INDICATION FOR USE

The BASHIR™ Endovascular Catheter and BASHIR™ S-B Endovascular Catheter are mechanical thrombolysis catheters indicated for the:

- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism.
- Infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus.

6. INTENDED USE COMPARED TO THE PREDICATE

The intended use of the BASHIR™ and the BASHIR™ S-B Endovascular Catheters is the same as that of the predicate device, Ekosonic Endovascular Device (K211080): They are mechanical thrombolysis catheters intended to infuse physician-specified fluids into a thrombus in either the peripheral or pulmonary circulation and for treatment of pulmonary embolism.

The indication for use for the subject devices has been expanded to include use in the pulmonary arteries to treat pulmonary embolism. The use of the BASHIR™ and BASHIR™ S-B Endovascular Catheters for treatment of pulmonary embolism were evaluated in the First-in-Human study and the pivotal RESCUE Clinical Trial, and the results support a substantially equivalent safety and effectiveness profile to the predicate device.

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

The BASHIR™ and the BASHIR™ S-B Endovascular Catheters have technological similarities to the predicate device (i.e., general catheter dimensions, catheter placement, compatibility with fluids, biocompatible nature of materials, radiopacity, and hydraulic mechanism for fluid dispersion). The subject and predicate devices differ in that the predicate device is a software-controlled device, whereas the subject devices are mechanical in nature and do not require capital equipment. The two reference devices (BASHIR™ and the BASHIR™ S-B Endovascular Catheters, K211061 and K192598) are technologically identical to the subject devices.

8. PERFORMANCE TESTING

This 510(k) provides clinical performance data to support the expanded indication for use for treatment of pulmonary embolism and to establish the substantial equivalence of the BASHIR™ and the BASHIR™ S-B Endovascular Catheters to the predicate device.

Biocompatibility: Biocompatibility evaluation has been performed to show the finished, sterilized device is biocompatible and suitable for its intended use according to 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." Testing included cytotoxicity, sensitization, intracutaneous toxicity, acute systemic toxicity, hemolysis, complement, and pyrogenicity testing. All tests passed.

Sterility: Sterilization validation studies were conducted with ethylene oxide sterilization to a Sterilization Assurance Level (SAL) of 10^{-6} CFU according to international standards. Bacteriostasis and fungistasis and ethylene oxide residual testing passed. All sterilization process parameters met the established protocols and the requirements were satisfied.

Performance Testing - Bench: Thrombolex conducted design validation testing and human factors testing and showed that the subject devices meet product requirements and design specifications. Simulated use studies over 20 hours confirmed functionality of the subject device over 20 hours. Performance testing included an evaluation of: Kink radius, trackability, advancement force, slider actuator force, catheter retraction, radial force, delivery flow rate, infusion pressure through various lumens and at various flow rates, guidewire compatibility, dimensional verification, compliance of injection hubs, air leakage, fluid leakage, stress cracking, resistance to separation, torque strength, corrosion resistance, joint tensile strength and particulate generation.

Thrombolex performed an In-Use Study to evaluate the cumulative impact of in-use materials and conditions on the product quality attributes of a representative drug, before vs. after the fluid was infused through the subject device at a rate and concentration representative of those used in clinical trials. Testing demonstrated no impact on the device or the pharmacological fluid.

Performance Testing – Animal: Thrombolex performed a GLP animal study of deployment of the BEC in the peripheral vasculature and the pulmonary artery in a swine model. The BASHIR™ Endovascular Catheter had no adverse effects systemically, on gross or histopathology evaluation, and resulted in no animal mortality.

Performance Testing – Clinical: A First in Human (FIH) with 9 patients and pivotal study with 109 patients were conducted for the BASHIR™ Endovascular Catheter. Please refer to published literature for appropriate use of the BASHIR™ Endovascular Catheter in pulmonary endovascular cases.

9. CONCLUSIONS

The information presented in this 510(k) submission demonstrates that the BASHIR™ and the BASHIR™ S-B Endovascular Catheters are substantially equivalent to the predicate device and supports the use of these devices in the pulmonary artery for treatment of pulmonary embolism and in the peripheral circulation for the restoration of blood flow in patients with venous thrombus.