February 3, 2022

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

Re: K211061
Trade/Device Name: BASHIR Endovascular Catheter, Reference No. 7201 and BASHIR Plus Endovascular Catheter, Reference No. 7210, 7220, 7230, 7240 (BASHIR+10, BASHIR+20, BASHIR+30, BASHIR+40)
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 June 10, 2021. 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 14:32:24 -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

June 10, 2021

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

Re: K211061
Trade/Device Name: BASHIR Endovascular Catheter (Ref. 7201), BASHIR Plus 10 Endovascular Catheter (Ref. 7210), BASHIR Plus 20 Endovascular Catheter (Ref. 7220), BASHIR Plus 30 Endovascular Catheter (Ref. 7230), BASHIR Plus 40 Endovascular Catheter (Ref. 7240)
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA
Dated: April 8, 2021
Received: April 9, 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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.06.10 12:43:23 -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: *K211O61*

Device Name
BASHIR™ Endovascular Catheter and BASHIR™ Plus Endovascular Catheters (BASHIR™+10, BASHIR™+20, BASHIR™+30, BASHIR™+40)

Indications for Use *(Describe)*
The BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheters (BASHIR™+10, BASHIR™+20, BASHIR™+30, BASHIR™+40) are intended for the controlled and selective 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 8, 2021

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

BASHIR™ Endovascular Catheter, Reference No. 7201
BASHIR™ Plus Endovascular Catheter, Reference No. 7210, 7220, 7230, 7240
(BASHIR™ +10, BASHIR™+20, BASHIR™+30, BASHIR™+40)

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:	II
Product Code:	KRA – Continuous Flush Catheter
Panel:	Cardiovascular

3. PREDICATE DEVICE

The predicate devices are the BASHIR™ Endovascular Catheter, K183290 and the BASHIR™ Plus Endovascular Catheters, K193071.

4. DESCRIPTION OF THE DEVICE

The BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheter are continuous flush catheters designed to enable delivery of physician-specified fluids, including thrombolytics, into the peripheral circulation. There is one model of the BASHIR™ Endovascular Catheter (Ref. No. 7201) and four models of the Bashir™ Plus Endovascular Catheter, (Ref. No. 7210, 7220, 7230, 7240). The design of the catheters allow for delivery and positioning of the catheter at the target peripheral location via a sheath, over a guidewire using fluoroscopic guidance. The infusion can be initiated into a distal infusion basket via the Basket Port 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. When the infusion basket is expanded into a clot, the clot is fragmented and a channel created, providing an opportunity for restoration of endogenous blood flow. The physician-specified solution is delivered via multiple laser-drilled holes through the infusion limbs of the catheters after placement.

The BASHIR™ Plus Endovascular Catheters have a second Shaft Port, for delivery of infusion solutions into the shaft lumen adjacent to the infusion basket where multiple laser-drilled holes extend over 10 cm (BASHIR+10), 20 cm (BASHIR+20), 30 cm (BASHIR+30) or 40 cm (BASHIR+40) of shaft length.

After the completion of solution delivery, the infusion limbs are collapsed to a closed position and the BASHIR™ Endovascular Catheter and/or BASHIR™ Plus Endovascular Catheter are retracted into the sheath and removed.

The catheters are comprised of common materials used in vascular catheters. The catheters are mechanical and contain no electrical components.

5. INTENDED USE / INDICATION FOR USE

The BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheters (BASHIR™+10, BASHIR™+20, BASHIR™+30, BASHIR™+40) are intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus.

6. COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The Intended Use statement is identical to that of the predicate devices with the exception of adding a specific indication for use, as an example of the types of patients that can be treated with the BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheters. The modification, addition of the wording “enabling the restoration of blood flow in patients with venous thrombus,” is an example of the patient population to be treated.

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

The BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheters are identical in design, operational and technological characteristics and supports that no new safety concerns are being raised by change in the Intended Use/Indications for Use statement and thus raises no new issues of safety or effectiveness.

8. PERFORMANCE TESTING

The BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheters were previously subjected to a comprehensive test program that included animal and bench testing, biocompatibility, sterilization and packaging testing. Clinical data for the treatment of venous thrombus, already included in the intended use of the device, support the additional wording in the intended use statement as summarized below:

Clinical Evidence: Sequential case information from Real-World use of the BASHIR™ Endovascular Catheter and the range of BASHIR™ Plus Endovascular Catheters in 15 different institutions provides evidence for expanding the labeling to include the indication for use in patients with venous thrombus. The devices were used to successfully treat 45 patients with venous thrombus (primarily iliofemoral thrombus) with either complete or partial resolution of venous thrombus, with no bleeding or other adverse events.

9. CONCLUSIONS

In summary, the Real-World clinical information presented in this 510(k) submission supports the additional indications for use wording for the BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheters to restore blood flow in patients with venous thrombus, and raises no new issues of safety or effectiveness, leading to the conclusion of substantial equivalence to the predicate devices.