



U.S. FOOD & DRUG
ADMINISTRATION

February 3, 2022

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

Re: K193071

Trade/Device Name: Bashir Plus Endovascular Catheter
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 December 17, 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
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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



December 17, 2019

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

Re: K193071

Trade/Device Name: Bashir Plus Endovascular Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: November 1, 2019
Received: November 4, 2019

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

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Gregory W. O'Connell -S
Date: 2019.12.17
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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

Indications for Use

510(k) Number (if known)

K193071

Device Name

Bashir™ Plus Endovascular Catheter

Indications for Use (Describe)

The Bashir™ Plus Endovascular Catheters are 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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"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."



510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Thromborex, 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

November 1, 2019

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

Bashir™ Plus Endovascular Catheter, Reference No. 7210, 7220, 7230, 7240

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™ Plus Endovascular Catheter is a continuous flush catheter designed to enable delivery of physician-specified fluids, including thrombolytics, into the peripheral circulation. There are four models of the Bashir™ Plus Endovascular Catheter, (Ref. No. 7210, 7220, 7230, 7240). The design of the Bashir™ Plus 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 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. The physician-specified solution is delivered via multiple laser-drilled holes through the infusion limbs of the Bashir™ Plus Endovascular Catheter after placement.

The Bashir™ Plus Endovascular Catheter has a second Shaft Port, for delivery of infusion solutions into the shaft lumen where multiple laser-drilled holes cover 10 cm of length (Ref. No. 7210), 20 cm (Ref. No. 7220), 30 cm (Ref. No. 7230) or 40 cm (Ref. No. 7240).

After the completion of solution delivery, the infusion limbs are collapsed to a straight position and then the Bashir™ Plus Endovascular Catheter is retracted into the sheath and removed.

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