THROMBOLEX®

MECHANICALLY CHANNELED THROMBOLYSIS

# Value Analysis Packet

Mechanically channeled thrombolysis for pulmonary, peripheral vascular or venous thrombus. Complete documentation for value analysis committee review — regulatory, clinical, product, economic.

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**THROMBOLEX® 7Fr and 8Fr Endovascular Devices**

FDA-cleared Mechanical Thrombolysis Catheter · 21 CFR 870.5150 Class II

The complete submission set for value analysis committee review.

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**Prescription device.** Federal (USA) law restricts these devices to sale by or on the order of a physician. Refer to the Instructions for Use for complete indications, contraindications, warnings and precautions. Not a substitute for the Instructions for Use, product labeling, or clinical judgment.

This document provides recommendations for use of the THROMBOLEX device only and is not intended to replace device Instructions for Use (IFU), product labeling, clinical judgment, or institutional protocols. Treatment decisions should be individualized based on patient-specific factors and physician discretion. Refer to the device IFU for complete safety information, indications, contraindications, and usage.

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# Indication for use and regulatory clearance.

The THROMBOLEX® procedure treats pulmonary, peripheral vascular and venous thrombus.

## INDICATIONS FOR USE — AS CLEARED

| DEVICES | CLEARED INDICATIONS FOR USE |
|---|---|
| **7Fr · 7Fr S-B**<br>**8Fr · 8Fr S-B** | Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism.<br><br>Infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus. |
| **7Fr +10 · +20 · +30 · +40** | 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. |

These are **two separately cleared indications** and are stated separately; they are not a single combined indication. **The clearance letters reproduced in the appendix carry the device names as filed with FDA.** THROMBOLEX is the commercial name for the same cleared devices — models, reference numbers and cleared indications are unchanged.

## ANATOMY TREATED

| CATEGORY | VESSELS |
|---|---|
| **Pulmonary embolism** | Pulmonary trunk · right and left pulmonary arteries · lobar and segmental branches |
| **Venous thrombus** | Iliocaval (including IVC-filter–associated) · iliofemoral · femoral · brachial · subclavian · axillary |
| **Peripheral vascular thrombus** | Aortic · iliac · femoral · popliteal · tibial |

## CLEARANCE SUMMARY

| DEVICE | MODEL | 510(K) | CLEARED |
|---|---|---|---|
| **THROMBOLEX 7Fr** | 7201 | **K222095** | 20 Apr 2023 |
| **THROMBOLEX 7Fr S-B** | 7101 | **K222095** | 20 Apr 2023 |
| **THROMBOLEX 8Fr** | 8201 | **K231653** | 3 Jul 2023 |
| **THROMBOLEX 8Fr S-B** | 8101 | **K231653** | 3 Jul 2023 |
| **THROMBOLEX 7Fr +10 · +20 · +30 · +40** | 7210–7240 | **K211061** | 10 Jun 2021 |

Every clearance letter is reproduced without alteration in the appendix to this packet.

## CLASSIFICATION

| 510(K) | REGULATION | DEVICE CLASS AND PANEL | PRODUCT CODES |
|---|---|---|---|
| **K222095** | 21 CFR 870.5150<br>embolectomy catheter | Class II · cardiovascular | QEY · KRA |
| **K231653** | 21 CFR 870.5150<br>embolectomy catheter | Class II · cardiovascular | QEY · KRA |
| **K211061** | 21 CFR 870.1210<br>continuous flush catheter | Class II · cardiovascular | QEY · KRA |

K211061 sits under a **different regulation number** and also covers Ref. 7201. Additional clearances in the device history: K183290, K192598, K193071. No capital equipment, console, generator or service agreement is associated with any clearance.

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# Mechanically channeled thrombolysis — what the device actually does.

A single-use, over-the-wire catheter with an expandable nitinol basket. The basket channels the thrombus and pulse-sprays the thrombolytic into it rather than around it. **The device channels; the delivered lytic dissolves.**

## MECHANISM OF ACTION

### Fissures the clot and delivers targeted lytic therapy

Mechanical expansion of six mini-infusion catheters creates fissures in the thrombus and increases the surface area over which lytic is delivered.

### Dissolves main and downstream thrombus

Basket expansion establishes channels through the clot; infusion delivers lytic into the thrombus rather than around it.

### Restores patency in distal segmental branches

Segmental occlusion reduction was the only level that correlated with RV/LV recovery (P=0.0026).[1]

## OPERATIONAL SIMPLICITY

### Repeatable, streamlined workflow

Fixed sequence and fixed total dose. Procedural success 50 of 50; 96% treated bilaterally with the same workflow.[2]

### Defined procedural stopping point

The total dose is set before the procedure begins. Nothing is left infusing when the case ends, and no second procedure is required to remove hardware.

### OTT procedure does not require routine ICU admission

No prolonged infusion. 92% of patients required no ICU care at any point (46 of 50).[2]

## SUGGESTED ON-THE-TABLE (OTT) WORKFLOW — PULMONARY EMBOLISM

| STEP | WHAT HAPPENS | DOSE AND DELIVERY |
|---|---|---|
| **01 Access & position** | Single 7Fr or 8Fr venous access; the device tracks over a 0.018″ (7Fr) or 0.035″ (8Fr) guidewire | — |
| **02 Expand & pulse spray** | Basket expands and channels the thrombus; thrombolytic is pulse-sprayed through the basket ports; basket collapses | **1 mg dilute r-tPA** |
| **03 Expand & pulse spray** | Basket expands; heparinized saline flush is pulse-sprayed through the basket ports; basket collapses | **10 cc heparinized saline** |
| **04 Repeat to fixed dose** | Sequence repeats to the pre-set total dose, one pulmonary artery at a time | **4 mg r-tPA per pulmonary artery**<br>**4 mg unilateral · 8 mg bilateral** |
| **05 Collapse & remove** | Basket collapses and the device is removed. Session complete — no required infusion follows | No infusion follows |

Suggested workflow only, as studied in RAPID-PE.[2] Not a substitute for the Instructions for Use, product labeling, or clinical judgment. “Channels” refers to flow-channel restoration, not clot removal; lysis is performed by the delivered thrombolytic.

1. RESCUE occlusion and RV/LV core-lab sub-analysis, *JACC Adv.* 2023;2(9):100670 (n=107 of 109). 2. RAPID-PE pre-specified interim analysis of the first 50 of 150 patients enrolled; presented at TCT 2025 — interim data, not peer-reviewed.

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# Three studies. Results are reported by study and are not pooled.

Protocols, doses and populations differ between these studies; results are not pooled and no between-study comparison is implied or supported.

## EVIDENCE

| STUDY | N | WHAT IT ESTABLISHES |
|---|---|---|
| **RESCUE**<br>NIH/NHLBI pivotal IDE | 109 | Segmental occlusions −71.1%, proximal PA −61.3%, RV/LV −33.3% at 48 h, all P<0.0001. Core-lab assessed, 18 U.S. sites. |
| **RESCUE-II**<br>On-the-table feasibility | 9 | 8 mg bolus, no post-procedure infusion, one device per patient. RV/LV −22.3%; lysis reached branches remote from the infusion device. |
| **RAPID-PE**<br>OTT multicenter, enrolling | 50 | Procedural success 50 of 50 across 17 operators. Deaths or hemodynamic decompensation at 7 days: 0 of 50. 30-day mortality 0. |

## SAFETY — REPORTED SEPARATELY BY STUDY, NEVER POOLED

| | RESCUE (109) | RESCUE-II (9) | RAPID-PE (50) |
|---|---|---|---|
| **ISTH major bleeding within 72 h** | <1% (1) · access site | 0 | 2% (1) · access site |
| **Intracranial hemorrhage** | 0 | 0[2] | 0 |
| **Device-related event** | 1 · left common iliac vein thrombosis | 0 | 0 |
| **30-day mortality** | 1 · non-PE cause | 0 | 0 |

**Every bleeding event across the three studies was an access-site event.** No intracranial or pulmonary-arterial bleeding was reported in any study. In RESCUE the single major bleed and the device-related iliac vein thrombosis occurred in the same patient, who was off anticoagulation.

**Scope.** The studies above are pulmonary embolism studies. The peripheral vascular and venous thrombus indication is separately cleared.

**RAPID-PE figures are from the pre-specified interim analysis of the first 50 of 150 patients enrolled, presented at TCT 2025 and not yet published. The full 150-patient dataset is to be presented at The VEINS, October 2026.** 1. RESCUE Bashir R, et al. *JACC Cardiovasc Interv.* 2022;15(23):2427–2436; occlusion and RV/LV sub-analysis *JACC Adv.* 2023;2(9):100670 (n=107 of 109). RESCUE-II Lakhter V, et al. *JACC Adv.* 2025;4(6):101789. RAPID-PE Jaber WA, et al. TCT 2025. 2. RESCUE-II did not report ICH as a separate outcome; ISTH major bleeding, which encompasses it, was zero.

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# Specifications and catalog.

Basket dimensions are reported **open and closed**.

### THROMBOLEX 7FR · 0.018″ GUIDEWIRE

| | THROMBOLEX 7FR · #7201 | THROMBOLEX 7FR S-B · #7101 |
|---|---|---|
| **Catheter diameter** | 7Fr | 7Fr |
| **Infusion basket — open** | 10 cm × 45 mm | 7.5 cm × 39 mm |
| **Infusion basket — closed** | 12.5 cm × 2.3 mm | 10 cm × 2.3 mm |
| **Effective length** | 90 cm open · 92.5 cm closed | 90 cm open · 92.5 cm closed |
| **Guidewire compatibility** | 0.018″ | 0.018″ |

### THROMBOLEX 8FR · 0.035″ GUIDEWIRE

| | THROMBOLEX 8FR · #8201 | THROMBOLEX 8FR S-B · #8101 |
|---|---|---|
| **Catheter diameter** | 8Fr | 8Fr |
| **Infusion basket — open** | 10 cm × 45 mm | 7.5 cm × 39 mm |
| **Infusion basket — closed** | 12.5 cm × 2.3 mm | 10 cm × 2.3 mm |
| **Effective length** | 90 cm open · 92.5 cm closed | 90 cm open · 92.5 cm closed |
| **Guidewire compatibility** | 0.035″ | 0.035″ |

### THROMBOLEX 7Fr +10 THROUGH +40 — EXTENDED SHAFT INFUSION

| DEVICE | ITEM # | SHAFT INFUSION SEGMENT | BASKET |
|---|---|---|---|
| **THROMBOLEX 7Fr +10** | 7210 | 10 cm · 42 laser-drilled holes | Same as #7201 |
| **THROMBOLEX 7Fr +20** | 7220 | 20 cm · 42 laser-drilled holes | Same as #7201 |
| **THROMBOLEX 7Fr +30** | 7230 | 30 cm · 42 laser-drilled holes | Same as #7201 |
| **THROMBOLEX 7Fr +40** | 7240 | 40 cm · 56 laser-drilled holes | Same as #7201 |

All devices: six mini-infusion catheters with 48 precision laser-drilled holes in the basket; basket expansion physician-controlled via the actuator.

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# Payment figures supplied. Cost inputs entered by the hospital.

## FIGURES SUPPLIED BY THROMBOLEX

| FIGURE | WHAT IT COVERS | BASIS |
|---|---|---|
| $0 | **Capital equipment** | No console, generator, pump or capital purchase at any point in the program. |
| $0 | **Proprietary disposable circuit** | The device is over-the-wire and physician-actuated. Nothing else is required to run it. |
| $0 | **Service contract or preventive maintenance** | No serviceable equipment, therefore no service relationship. |
| $0 | **Post-procedure lytic infusion** | Fixed total dose delivered in the lab. Nothing is left infusing and no hardware is left in place. |

These four are verifiable product facts. Every other figure in the budget impact — device acquisition, thrombolytic, comparator cost, case volume — is entered by the hospital.

MS-DRG assignment is determined by the coded procedure and diagnosis, not by device selection. Actual payment varies by hospital. THROMBOLEX makes no claim regarding the cost, performance or economics of any other product; all comparative figures are supplied by the user. THROMBOLEX does not guarantee coverage or payment.

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# Code and MS-DRG assignment.

MS-DRG assignment is driven by the coded diagnosis paired with a **Fragmentation procedure code, percutaneous approach**. Figures are FY 2027, effective for discharges 1 October 2026 through 30 September 2027.

## MS-DRG ASSIGNMENT · FY 2027

| DRG | DESCRIPTION | RELATIVE WEIGHT | NATIONAL UNADJUSTED | APPLIES TO |
|---|---|---|---|---|
| **173** | Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism | 2.9556 | **$21,836** | Pulmonary embolism |
| **278** | Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures *with* MCC | 6.3466 | **$46,888** | Peripheral vascular (venous & arterial) |
| **279** | Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures *without* MCC | 4.1313 | **$30,522** | Peripheral vascular (venous & arterial) |

Payment = relative weight × (operating standardized amount $6,848.00 + capital federal rate $539.95) = weight × **$7,387.95**. CMS FY 2027 IPPS Final Rule (CMS-1849-F, as corrected by CMS-1849-CN3), Tables 1A, 1D, and 5. National unadjusted — excludes wage index, IME, DSH/UCP, outlier, NTAP and the 2% sequestration reduction. **MS-DRG 173 has no severity split** — assignment and weight are the same with or without a major complication or comorbidity.

## ICD-10-PCS — FRAGMENTATION, PERCUTANEOUS APPROACH

| BODY SYSTEM | CODES | MS-DRG |
|---|---|---|
| **Pulmonary vessels** | 02FP3ZZ · 02FQ3ZZ · 02FR3ZZ · 02FS3ZZ · 02FT3ZZ<br>Pulmonary trunk · right and left pulmonary artery · right and left pulmonary vein | **173** |
| **Peripheral arteries** | Upper 03F23ZZ–03FC3ZZ · 03FY3ZZ  Lower 04FC3ZZ–04FU3ZZ · 04FY3ZZ | **278 · 279** |
| **Peripheral veins** | Upper 05F33ZZ–05FF3ZZ · 05FY3ZZ  Lower 06FC3ZZ–06FQ3ZZ · 06FY3ZZ | **278 · 279** |

## ICD-10-CM DIAGNOSIS CODES — REPRESENTATIVE, NOT EXHAUSTIVE

| GROUP | CODES |
|---|---|
| **Pulmonary vessels** | I26.02 · I26.09 (with acute cor pulmonale) · I26.92 · I26.99 (without) |
| **Thoracic and peripheral veins** | I82.290 · I82.401–.403 · I82.409 |
| **Peripheral and other arteries** | I74.2–I74.5 · I74.8 · I74.9 |

Codes are representative, not exhaustive; ranges abbreviate the full laterality and vessel-specific series. Relative weights are CMS FY 2027 (Table 5, IPPS Final Rule) and are updated annually. **MS-DRG assignment is determined by the coded procedure and diagnosis, not by device selection; actual payment varies by hospital.** Providers are responsible for accurate coding and for verifying current codes, weights and rates. THROMBOLEX does not guarantee coverage or payment.

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# Implementation requirements.

The device is a single-use, over-the-wire, physician-actuated catheter. There is no equipment to commission, no software to validate and no environment to modify.

## DEPARTMENTS THAT ARE NOT AFFECTED

| FUNCTION | ACTION | WHY |
|---|---|---|
| **Biomedical engineering** | **None** | No capital equipment to intake, tag, inventory or schedule for preventive maintenance. |
| **Information technology / security** | **None** | No software, no network connection, no patient data, no cybersecurity review. |
| **Facilities** | **None** | No power, gas, mounting or floor-space requirement in the interventional suite. |
| **Pharmacy** | Existing | Thrombolytic is drawn from existing stock at the protocol dose. No new agent is introduced. |
| **Sterile processing** | **None** | Single use. No reprocessing, no tray build, no loaner instrumentation. |

## TRAINING AND IN-SERVICE

### Physician training

Delivered by the sales team at the account. The procedure uses standard access and standard over-the-wire technique; the device-specific step is basket actuation.

### Lab and nursing staff

In-service covers device preparation and the pulse-spray sequence. No new monitoring equipment and no post-procedure infusion to manage on the floor.

## SUPPLY AND INVENTORY

| ATTRIBUTE | SPECIFICATION |
|---|---|
| **Unit of measure** | Each. Suggested initial order quantity 8 catheters (2 cartons). |
| **Sterilization** | Sustainable ethylene oxide gas. Single use — do not reprocess. |
| **Shelf life** | 3 years from date of manufacture. |
| **Storage** | Ambient. No cold chain, no controlled-substance handling, no dedicated cabinet. |
| **Devices per case** | One device per patient in RESCUE-II and RAPID-PE. |

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# Contents and clearance summary.

Three 510(k) clearances cover the platform. **The clearance letters carry the device names as filed with FDA.** THROMBOLEX is the commercial name for the same cleared devices — models, reference numbers and cleared indications are unchanged.

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## CLEARANCE SUMMARY

| DEVICE | MODEL / REF. | 510(K) | CLEARED |
|---|---|---|---|
| **THROMBOLEX 7Fr** | 7201 | K222095 | 20 Apr 2023 |
| **THROMBOLEX 7Fr S-B** | 7101 | K222095 | 20 Apr 2023 |
| **THROMBOLEX 8Fr** | 8201 | K231653 | 3 Jul 2023 |
| **THROMBOLEX 8Fr S-B** | 8101 | K231653 | 3 Jul 2023 |
| **THROMBOLEX 7Fr +10 · +20 · +30 · +40** | 7210–7240 | K211061 | 10 Jun 2021 |

K222095 and K231653 were cleared under **21 CFR 870.5150, embolectomy catheter**, Class II, product codes QEY and KRA. **K211061 was cleared under 21 CFR 870.1210, continuous flush catheter** — a different regulation number, and it also covers Ref. 7201. Additional clearances in the device history: K183290, K192598, K193071. Cardiovascular panel throughout.

## INDICATIONS FOR USE — AS CLEARED

| DEVICES | CLEARED STATEMENT |
|---|---|
| **7Fr · 7Fr S-B · 8Fr · 8Fr S-B** | Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism.<br>Infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus. |
| **7Fr +10 · +20 · +30 · +40** | 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. |

These are two separately cleared indications and are stated separately; they are not a single combined indication. **Reproduced as issued.** FDA clearance letters and the IRS Form W-9 are reproduced without alteration. Image quality reflects the source file; originals are available from Regulatory on request. **Prescription device.** Refer to the Instructions for Use for complete indications, contraindications, warnings and precautions.

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## K222095 — THROMBOLEX 7Fr and 7Fr S-B



U.S. FOOD & DRUG ADMINISTRATION

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

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10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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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 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

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## K222095 — THROMBOLEX 7Fr and 7Fr S-B



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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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## K231653 — THROMBOLEX 8Fr and 8Fr S-B



FDA U.S. FOOD & DRUG ADMINISTRATION

July 3, 2023

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

Re: K231653
Trade/Device Name: BASHIR™ .035 Endovascular Catheter, BASHIR™ S-B .035 Endovascular Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEY, KRA
Dated: June 5, 2023
Received: June 6, 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.

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TAP014-00 Rev I

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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: 2023.07.03 11:20:26 -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

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## K231653 — THROMBOLEX 8Fr and 8Fr S-B



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)*
K231653

Device Name
BASHIR™ .035 Endovascular Catheter
BASHIR™ S-B .035 Endovascular Catheter

Indications for Use *(Describe)*
The BASHIR™ .035 Endovascular Catheter and BASHIR™ S-B .035 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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

**FORM FDA 3881 (6/20)** Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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## K211061 — THROMBOLEX 7Fr and +10 through +40



U.S. FOOD & DRUG ADMINISTRATION

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.

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

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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.

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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
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Enclosure

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## K211061 — THROMBOLEX 7Fr and +10 through +40



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: *K211061*

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.**

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Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

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**FORM FDA 3881 (6/20)** Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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## IRS Form W-9

Request for Taxpayer Identification Number and Certification

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

**Request for Taxpayer Identification Number and Certification**

**Go to *www.irs.gov/FormW9* for instructions and the latest information.**

**Give form to the requester. Do not send to the IRS.**

**Before you begin.** For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

**Print or type.** See ***Specific Instructions*** on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

Thrombolex, Inc.

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☒ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☐ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) . . . .

**Note:** Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

*(Applies to accounts maintained outside the United States.)*

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions . . . . . ☐

5 Address (number, street, and apt. or suite no.). See instructions.

4416 NJ-27, Suite B

Requester's name and address (optional)

6 City, state, and ZIP code

Kingston, NJ 08528

7 List account number(s) here (optional)

### Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

**Note:** If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

**Social security number**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | – | | | – | | | | |

**or**

**Employer identification number**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8 | 1 | – | 2 | 8 | 3 | 7 | 9 | 1 | 0 |

### Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

**Certification instructions.** You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

**Sign Here** | **Signature of U.S. person** | **Date** 01/21/2026

## General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

**Future developments.** For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

### What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

### Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

Cat. No. 10231X

Form **W-9** (Rev. 3-2024)

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