December 22, 2020

Vetex Medical, Ltd.
Mark Bruzzi
CEO
Business Innovation Center, NUI Galway
Newcastle Road
Galway, Ireland

Re: K201705
Trade/Device Name: ReVene Thrombectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: November 23, 2020
Received: November 24, 2020

Dear Mark Bruzzi:

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 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)*
K201705

Device Name
ReVene Thrombectomy Catheter

Indications for Use *(Describe)*
The device is indicated for mechanical de-clotting and controlled and selective infusion of physician specified fluids, including thrombolytics, in 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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## 510(k) Summary

| | |
|---|---|
| Submitter: | Vetex Medical Ltd.,<br>Business Innovation Centre,<br>NUI, Galway, Newcastle Road,<br>Galway, Ireland |
| Contact person: | Mark Bruzzi<br>CEO<br>Tel: +353 91 394795 |
| Date Summary was prepared: | 18 Dec 2020 |
| Trade Name: | ReVene Thrombectomy Catheter |
| 510(k) Number | K201705 |
| Common/Usual Name: | Thrombectomy catheter |
| Classification Name: | Continuous Flush Catheter, (21 CFR 870.1210, product code KRA)<br>Embolectomy Catheter, (21 CFR 870.5150, product code QEW) |
| Predicate device: | The Cleaner Rotational Thrombectomy System (K141617).<br>This predicate device has not been subject to a design-related recall. |
| Reference devices: | No reference devices were used in this submission |

**Device Description**

The ReVene Thrombectomy Catheter is a rotational venous thrombus extraction system for the treatment of vessels greater than 6mm diameter. The device is designed to be used in a medical catheter laboratory and allows for optional infusion of thrombolytic agents.

The device is compatible with a 10Fr introducer and includes a wire-braided cobalt chromium basket for thrombus disruption. A rotational thrombus-extractor, consisting of a helical coil housed inside a metal tube, is powered by an internal DC motor and batteries. The extractor runs the length of the catheter, and when activated, the coil rotates and is designed to macerate and transport thrombus from the basket to a collection container outside the body.

The main features of device are:

- The thrombus disruption cage
- The non-vessel contact thrombus extractor
- The handle

The ReVene Thrombectomy Catheter is packaged as a single unit and is sterilized using ethylene oxide. The device is provided sterile, non-pyrogenic and is for single-use only.

## Indications for Use

The ReVene Thrombectomy Catheter is indicated for mechanical de-clotting and controlled and selective infusion of physician specified fluids, including thrombolytics in the peripheral vasculature. The Indications for Use statement is identical to the predicate device.

### Comparison of Technological Characteristics with the Predicate Device

The ReVene Thrombectomy Catheter is substantially equivalent to the Cleaner Rotational Thrombectomy System (K141617) in its intended use, principles of operation, design, materials, and sterile package configuration. The design differences have been evaluated through pre-clinical in vitro and in vivo testing.

**Table 1: Substantial Equivalence Comparison: ReVene versus Predicate Device**

| Attribute | ReVene Thrombectomy Catheter | Cleaner Rotational Thrombectomy System (Cleaner XT and Cleaner 15) (K141617) |
|---|---|---|
| Intended Use | The device is intended for mechanical de-clotting and controlled and selective infusion of physician specified fluids, including thrombolytics, in the peripheral vasculature. | Same |
| Indications for use | The device is intended for mechanical de-clotting and controlled and selective infusion of physician specified fluids, including thrombolytics in the peripheral vasculature. | Substantially equivalent.<br>Mechanical de-clotting of native vessel dialysis fistulae and synthetic dialysis access grafts.<br>Mechanical de-clotting and controlled and selective infusion of physician specified fluids, including thrombolytics, in the peripheral vasculature. |
| Device Class | Class II | Same |
| Product Code | KRA<br>QEW | KRA |
| Prescription Device | Yes | Same |
| Catheter Type | Mechanical Thrombectomy Catheter | Same |

| Attribute | ReVene Thrombectomy Catheter | Cleaner Rotational Thrombectomy System (Cleaner XT and Cleaner 15) (K141617) |
|---|---|---|
| Indicated Vessel Diameter | >6mm | Same |
| Sterilization Method | EtO | Same |
| Working Length | 90cm | Substantially equivalent: 65cm, 135cm |
| Rotating wire | Yes | Same |
| Power source | Battery | Same |
| Voltage | 9V | Same |
| Power activation | Switch located on handle | Same |
| Conditions of use | The device is used under fluoroscopy in a catheter lab | Same |
| Principle of operation | Mechanical clot disruption combined with extraction | Same |
| Access method | Access via introducer sheath | Same |
| Sheath compatibility | 10F | Substantially equivalent: 7F |
| Radiopacity | Radiopaque marker band on distal end | Substantially equivalent. Radiopaque distal tip and sinusoidal wire. |
| Energy source Location | Battery & motor in device handle | Same |

**Performance Testing**

Vetex Medical Ltd. developed a design verification and validation bench testing program to evaluate the performance and safety of the ReVene Thrombectomy Catheter and testing included:

- Packaging and labelling inspection
- Pouch peel testing
- Bubble leak testing
- Radial force testing
- Conformity assessment
- Catheter integrity testing:
    - Tensile testing
    - Compression testing
    - Torque resistance
    - Kink resistance
- Device visual & dimensional inspection
- Simulated Use testing
- Post-use inspection
- Corrosion testing
- Radiopacity testing
- Battery life testing

All tests met the pre-determined acceptance criteria. Aged testing has been performed to support a shelf-life of 12 months for the ReVene Thrombectomy Catheter.

**Biocompatibility Evaluation**

A biological evaluation was performed to evaluate the biological risks associated with the ReVene Thrombectomy Catheter per FDA's Guidance Use of International Standard ISO10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". Testing was performed in accordance in accordance with Good Laboratory Practices (GLP; 21 CFR Part 58) and results demonstrate the ReVene Thrombectomy Catheter is biocompatible for its intended use.

**Pre-Clinical Ovine Study**

The safety and performance of the ReVene Thrombectomy Catheter was successfully evaluated in an ovine model. The results demonstrate that the ReVene Thrombectomy Catheter will perform as intended.

**Clinical Trial**

The Venous Thrombus Extraction (VETEX) Clinical Study is an open label, prospective, non-randomized, multi-centre evaluation of the ReVene Thrombectomy Catheter for the treatment of acute iliofemoral deep vein thrombosis (DVT). A total of 19 subjects were enrolled and treated with the ReVene Thrombectomy Catheter. The Primary Performance Endpoint was met in 19/19 (100%) of subjects, with all subjects achieving a Society of Interventional Radiology (SIR) Grade II Lysis (50-95% thrombus removal) or greater in the target vessel, with freedom from procedural related adverse events. There were no

device-related adverse events in any subject. The ReVene Thrombectomy Catheter performed as intended in all cases when used per the instructions for use. Note: Although this study evaluated the ReVene Thrombectomy Catheter in patients with DVT, the device is not indicated for treatment of DVT in the US.

**Conclusion**

Test results demonstrated that all acceptance criteria were met, and therefore, the device conforms to established product specifications and intended use. Based upon the technology, materials, intended use, non-clinical testing, and animal study results, it is concluded that the ReVene Thrombectomy Catheter is substantially equivalent to the predicate device. These results demonstrate that the ReVene Thrombectomy Catheter does not raise new questions of safety and effectiveness.