February 23, 2023

Truvic Medical Inc.
% Semih Oktay
President
CardioMed Devices Consultants
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K223216
Trade/Device Name: Symphony Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: January 17, 2023
Received: January 17, 2023

Dear Semih Oktay:

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: 2023.02.23 12:59:49 -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

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)*
K223216

Device Name
Symphony Thrombectomy System

Indications for Use *(Describe)*

The Symphony Thrombectomy System is intended for:

- The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Symphony Thrombectomy System is intended for use in the peripheral vasculature.
It is not for use in the pulmonary 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.

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510(k) Summary
[as required by 21 CFR 807.87(h) and 21 CFR 807.92]

1359 Dell Avenue Campbell, CA 95008 USA

TRUVIC™ Symphony™ Thrombectomy System

510(k) K223216

Date Prepared:	16 Feb 2023
Applicant	TRUVIC Medical, Inc. 1359 Dell Avenue Campbell, CA 95008, USA
Contact	Rey Jacinto Associate Director, Regulatory Affairs Tel: (714) 357-8139 e-mail: rjacinto@TRUVIC.com
Trade Name:	Symphony™ Thrombectomy System
Device Classification:	Class 2 per 21 CFR §870.5150
Classification Name:	Peripheral Mechanical Thrombectomy With Aspiration
Product Code	QEW (Primary), KRA
Predicate Device:	Penumbra Embolectomy Aspiration System (INDIGO® Aspiration System); K142870

Intended Use / Indications for Use:
The TRUVIC Medical, Inc. (TRUVIC) Symphony Thrombectomy System is intended for:

- The non-surgical removal of fresh, soft emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The Symphony Thrombectomy System is intended for use in the peripheral vasculature. It is not for use in the pulmonary vasculature.

Device Description:
The Symphony Thrombectomy System is comprised of several devices:

- 24F Symphony Catheter
- 16F Symphony Catheter
- TRUVIC Generator
- 24F Symphony Dilator
- 16F Symphony Dilator
- TRUVIC Canister
- 24F Symphony Advance™ Long Dilator
- 16F Symphony ProHelix™
- TRUVIC Tubeset
- 24F Symphony ProHelix™

The Symphony Thrombectomy System is designed to remove thrombus/embolus (also referred to as 'thrombus' or 'clot') from the peripheral vasculature using controlled aspiration. The Symphony Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. The Symphony ProHelix may be used to facilitate aspiration and removal of the thrombus through the Symphony Catheter.

The Symphony Catheter has a lubricious hydrophilic coating on the distal 40 cm of the 24F catheter shaft, and distal 55 cm of the 16F catheter shaft. The Symphony Catheters and Symphony Dilators are introduced through a vascular access sheath into the peripheral vasculature and guided over a guidewire to the site of the thrombus. The Symphony Catheter is used with the TRUVIC Generator, connected using the TRUVIC Tubeset and the TRUVIC Canister, to aspirate thrombus.

As needed, the Symphony ProHelix may be introduced through the Symphony Catheter to assist with thrombus removal. The Symphony ProHelix is manually advanced through the Symphony Catheter over a guidewire, remaining inside the Symphony Catheter during the procedure. During aspiration, the handle on the proximal end of the Symphony ProHelix is manually rotated, which rotates the tip of the Symphony ProHelix to facilitate thrombus removal through the Symphony Catheter. The tips of the devices are visible under fluoroscopy.

Comparison with predicate device:
The subject device Symphony Thrombectomy System and the predicate Penumbra INDIGO System have the same intended use, operating principle, design concept, and sterilization processes. Both the subject and predicate systems utilize a catheter and wire-based device to facilitate thrombus removal, and both employ a continuous aspiration pump in this extraction function.

Table 1. Summary Comparison between the Symphony Thrombectomy System and the Indigo Aspiration System

	Subject Device	**Predicate Device**
Name of Device	Symphony Thrombectomy System	INDIGO Aspiration System
Manufacturer	TRUVIC Medical, Inc.	Penumbra, Inc.
510(k) #	K223216	K142870
Indications for Use	The Symphony Thrombectomy System is intended for: • The non-surgical removal of fresh, soft emboli and thrombi from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The Symphony Thrombectomy System is intended for use in the peripheral vasculature. It is not for use in the pulmonary vasculature.	The Penumbra Embolectomy Aspiration System (INDIGO® Aspiration System) is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. Not for use in the coronaries or the neurovasculature.
Product Code	QEW (Primary) KRA	QEW
Regulation Name/Number	21 CFR 870.5150 Embolectomy Catheters	21 CFR 870.5150 Embolectomy Catheters
Prescription/ Over-the-Counter Use	Prescription Only	Prescription Only
Single Use Only	Yes	Yes
Catheter Design	Single-Lumen Intravascular Catheter	Single-Lumen Intravascular Catheter
Catheter Dimensions (OD, Length)	16F, 121 cm 24F, 85 cm	5F, 136 cm 6F, 132 cm 8F, 85/115 cm
Thrombus Removal Assist Device	Over-the-Wire	Wire Based
Packaged Accessories	Dilator	RHV Introducer Sheath
User Control	Symphony Catheter Handle (On/Off and Vent)	Indigo Aspiration Tubing Switch (On/Off)

Vacuum Source	Aspiration Pump	Aspiration Pump
Radiopaque Markers	Yes	Yes
Hydrophilic coating	Yes	Yes
Hydrophobic coating	No	No
Sterilization Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)
System Materials	Commonly used medical grade plastics and metals	Commonly used medical grade plastics and metals
Shelf Life	Symphony Catheters and Dilators: 3 Months ProHelix: 7 Months	36 Months

Non-Clinical Testing / Performance Data:
Non-clinical laboratory testing was performed on the Symphony Thrombectomy System to assure compliance with all pre-specified, clinically relevant acceptance criteria and to determine substantial equivalence as it relates to the intended use. The following testing/assessments were performed:

- Visual and Dimensional Verification
- Kink / Bend Verification
- Actuation Force Verification
- Tensile and Torque Strength Verification
- Positive Pressure / Fluid Leak Verification
- Negative Pressure / Air Leak Verification
- Lumen Integrity Verification
- Burst Pressure Verification
- Fluoroscopy Validation (Visibility test)
- Simulated Use Performance Validation
- Corrosion Resistance Testing
- Coating Integrity Testing
- Acute Particulate Testing
- Drop Testing Verification
- Component Fatigue Testing Verification

The in vitro bench tests demonstrated that the Symphony Thrombectomy System met all acceptance criteria. Performance data demonstrate that the Symphony Thrombectomy System functions as intended and is substantially equivalent to the predicate device.

Biocompatibility:
Testing was performed to assess biocompatibility of the Symphony Thrombectomy System patient-contacting components. The following tests were successfully performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility
    - Direct and Indirect Hemolysis
    - Sc5b-9 Complement Activation
    - In-Vivo Thrombogenicity (from GLP animal study)

Adherence to the test methodologies and standards was maintained in all biocompatibility testing described. Each of the biocompatibility tests defined above passed. There was no evidence of toxicity, sensitization, or irritation. Testing found samples to be non-hemolytic, non-activator, and non-pyrogenic. All testing was conducted in compliance with GLP regulations, 21 CFR Part 58.

***In-Vivo* GLP Pre-Clinical Testing / Performance Data:**
A GLP animal study was performed to assess the acute and chronic safety and performance of the Symphony Thrombectomy System. *In-vivo* thrombogenicity was also assessed.

There were no complications in Symphony Thrombectomy System device preparation or performance and no vascular injuries were observed. All treated vessels were free from thrombus formation in both acute and chronic cohorts. All acceptance criteria passed. The GLP animal study did not identify any new questions of safety or effectiveness for the TRUVIC Symphony Thrombectomy System in all measured assessments, and supports substantial equivalence to the predicate device.

Conclusion:
The TRUVIC Symphony Thrombectomy System has the same intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, and operating principles as the predicate device. Performance data demonstrates that the device functions as intended. The non-clinical and *in-vivo* pre-clinical tests demonstrate that the Symphony Thrombectomy System is substantially equivalent to the predicate device.