May 14, 2025

Imperative Care, Inc.
Vida Sollanek
Sr. Manager, Regulatory Affairs, Vascular
1359 Dell Ave
Campbell, California 95008

Re: K250775
Trade/Device Name: Symphony™ Thrombectomy System; Symphony™ 16F 82cm Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: April 28, 2025
Received: April 28, 2025

Dear Vida Sollanek:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Digitally signed by
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For

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250775

Device Name
Symphony™ Thrombectomy System
Symphony™ 16F 82cm 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.

The Symphony 16F 82cm 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 16F 82cm 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.

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.

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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

A. Submitter Information

Submitter's Name:	Imperative Care, Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Vida Sollanek
Telephone:	917-892-8653
Email:	vsollanek@imperativecare.com
Date of Preparation:	March 13, 2025

B. Subject Devices

Proprietary Names:	Symphony™ Thrombectomy System; Symphony™ 16F 82cm Thrombectomy System
Classification Name:	Peripheral Mechanical Thrombectomy with Aspiration
Product Code:	QEW (Primary), KRA
Regulation:	21 CFR 870.5150

C. Predicate Device

Proprietary Name:	Symphony™ Thrombectomy System
Classification Name:	Peripheral Mechanical Thrombectomy with Aspiration
Product Code:	QEW (Primary), KRA
Regulation:	21 CFR. 870.5150
Manufacturer:	Imperative Care Inc.
510(k) #'s:	K223216

D. Intended Use / Indications for Use:

The indications for use are identical for the Symphony Thrombectomy System and for a line extension that created the Symphony 16F 82cm Thrombectomy System, except for the commercially branded names. They are presented separately to match the two Instructions for Use documents verbatim.

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 Symphony 16F 82cm 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 16F 82cm Thrombectomy System is intended for use in the peripheral vasculature. It is not for use in the pulmonary vasculature.

E. Device Description

The Symphony™ Thrombectomy System is comprised of several devices:

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

The Symphony™ 16F 82cm Thrombectomy System is comprised of several devices:

- 16F 82cm Symphony Catheter
- 16F 82cm Symphony Length Matched Dilator
- Symphony Clot Container
- TRUVIC Generator
- TRUVIC Canister
- TRUVIC Tubeset

Both Systems are designed to remove thrombus/embolus (also referred to as '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 16F Symphony Catheter or through the 24F Symphony Catheter. The Symphony ProHelix is not used with the 16F 82cm Symphony Catheter.

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 a Symphony 16F Catheter or a Symphony 24F Catheter to assist with thrombus removal. The Symphony ProHelix is not used with the 16F 82cm Symphony Catheter. 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.

F. Comparison with Predicate Device:

The subject devices, the Symphony Thrombectomy System and the Symphony 16F 82cm Thrombectomy System, and the predicate Symphony Thrombectomy System have the same intended use, operating principle, design concept, and sterilization processes. Both the subject systems and the predicate system utilize a catheter and wire-based device to facilitate thrombus removal, and both subject systems and predicate system employ a continuous aspiration pump in this extraction function.

Table 1. Summary Comparison between the Subject and Predicate Systems

	Predicate Device	Subject Devices
Name of Device	Symphony Thrombectomy System	Symphony Thrombectomy System Symphony 16F 82cm Thrombectomy System
Manufacturer	TRUVIC Medical, Inc.	Imperative Care, Inc.
510(k) #	K223216	K250775
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.	Same for the Symphony Thrombectomy System. The Symphony 16F 82cm System has the identical indications for use as the Symphony Thrombectomy System except for the commercially branded name of the 16F 82cm System.
Product Code	QEW (Primary) KRA	Same

	Predicate Device	Subject Devices
Regulation Name/Number	21 CFR 870.5150 Embolectomy Catheters	Same
Prescription/ Over-the-Counter Use	Prescription Only	Same
Single Use Only	Yes	Same
Catheter Design	Single-Lumen Intravascular Catheter	Same
Catheter Dimensions (OD, Length)	16F, 121 cm 24F, 85 cm	Symphony Thrombectomy System: Same Symphony 16F 82cm Thrombectomy System: 16F, 86 cm
Thrombus Removal Assist Device	Over-the-Wire	Same
Packaged Accessories	Dilator	Dilator, Symphony Clot Container
User Control	Symphony Catheter Handle (On/Off and Vent)	Same
Vacuum Source	Aspiration Pump	Same
Radiopaque Markers	Yes	Same
Hydrophilic coating	Yes	Same
Hydrophobic coating	No	Same
Sterilization Method	Ethylene Oxide (EO)	Same
System Materials	Commonly used medical grade plastics and metals	Same
Shelf life	Symphony Catheters: 3 months Symphony Dilators: 3 months Symphony ProHelix: 7 months	Symphony Catheters: 7 months Symphony Dilators: 7 months Symphony ProHelix: 25 months

G. Performance Data Supporting Substantial Equivalence:

Bench and laboratory (in-vitro) testing was performed on the subject 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 on the Symphony Thrombectomy System only for the changes made to the device and were leveraged for the Symphony 16F 82cm Thrombectomy System. The last two tests were characterization and were performed on the Symphony 16F 82cm Thrombectomy System only.

- Visual and Dimensional Verification
- Kink / Bend Verification
- Actuation Force Verification
- Tensile and Torque Strength Verification
- Bond Strength Verification
- Positive Pressure / Fluid Leak Verification
- Negative Pressure / Fluid Leak Verification
- Drop Testing Verification
- Component Fatigue Testing Verification
- Kink Characterization
- Torque Characterization

The following verification tests were leveraged from the predicate Symphony Thrombectomy System for the Symphony 16F 82cm Thrombectomy System:

- Lumen Integrity Verification
- Burst Pressure Verification
- Fluoroscopy Validation (Visibility test)
- Simulated Use Performance Validation
- Corrosion Resistance Testing
- Coating Integrity Testing
- Acute Particulate Testing

The in-vitro bench tests demonstrated that the subject Symphony Thrombectomy System and the subject Symphony 16F 82cm Thrombectomy System met all acceptance criteria. Performance data demonstrate that the subject devices function as intended and the changes do not raise any new questions of safety and/or effectiveness.

H. Biocompatibility

Testing was performed to assess biocompatibility of the subject Symphony Thrombectomy System and Symphony 16F 82cm Thrombectomy System patient-contacting components. The following tests were successfully performed:

- Cytotoxicity
- Hemocompatibility
- FTIR
- SEM Analysis

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 cytotoxicity. Testing found samples to be non-cytotoxic and non-hemolytic. All testing was conducted in compliance with GLP regulations, 21 CFR Part 58.

I. Sterilization

The Symphony Thrombectomy System and the Symphony 16F 82cm Thrombectomy System are sterilized using a validated Ethylene Oxide process with a sterility assurance level of $1x10^{-6}$ validated per the overkill method in accordance with ISO 11135, "Sterilization of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices".

J. Shelf Life and Packaging:

Accelerated aging testing based on ASTM F1980 was conducted to verify device, accessory, and packaging performance. A minimum shelf life was established based on this testing and is indicated by the expiration date provided on the product labeling. Verification testing of the subject devices followed the same test methods as the predicate device.

Packaging and sterile barrier integrity through transportation has been verified for the packaging configurations used for the subject devices. Aging testing has also been performed that supports the sterile barrier integrity following aging.

K. Conclusion:

Where differences were identified between the subject and predicate devices, a risk assessment was completed to determine if the differences would result in new questions of safety or effectiveness. As appropriate, previous bench and laboratory testing was evaluated for

applicability and either the rationale for no impact was documented or verification was repeated as required.

Based on the results of the risk assessments and associated bench and laboratory testing, the subject and predicate devices are substantially equivalent and there are no new questions of safety or effectiveness. The subject and predicate devices have the same intended use (except for the trade names), basic 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.

Therefore, the subject Symphony Thrombectomy System and subject Symphony 16F 82cm Thrombectomy System are both substantially equivalent to the predicate device.