August 28, 2025

Imperative Care, Inc.
Shivani Patel
Principal Regulatory Affairs Specialist
1359 Dell Ave
Campbell, California 95008

Re: K252057
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: June 30, 2025
Received: July 1, 2025

Dear Shivani Patel:

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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2025.08.28 09:04:19 -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

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)*
K252057

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 and for the treatment of pulmonary embolism.

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.

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510(k) Summary

I. SUBMITTER

Submitter's Name:	Imperative Care, Inc.
Address:	1359 Dell Avenue Campbell, CA 95008
Contact Person:	Shivani Patel
Telephone:	510-468-8862
Email:	spatel@imperativecare.com
Date of Preparation:	June 30, 2025

II. DEVICE

Proprietary Names:	Symphony™ Thrombectomy System and Symphony™ 16F 82cm Thrombectomy System
Common/Usual Name:	Embolectomy Catheter
Classification Name:	Peripheral Mechanical Thrombectomy with Aspiration
Regulatory Class:	II
Product Code:	QEW (Primary), KRA
Regulation	21 CFR 870.5150

III. PREDICATE DEVICE

Proprietary Name:	Symphony™ Thrombectomy System; Symphony™ 16F 82cm Thrombectomy System
Common/Usual Name:	Embolectomy Catheter
Classification Name:	Peripheral Mechanical Thrombectomy with Aspiration
Product Code:	QEW (Primary), KRA
Regulation:	21 CFR 870.5150
Manufacturer:	Imperative Care Inc.
510(k):	K250775

IV. INTENDED USE / INDICATIONS FOR USE

The indications for use for the subject Symphony Thrombectomy System are provided below.

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 and for the treatment of pulmonary embolism.

The indications for use are identical for the subject Symphony 16F 82cm Thrombectomy System and the predicate Symphony 16F 82cm Thrombectomy System.

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.

V. DEVICE DESCRIPTION

The Symphony™ Thrombectomy System is comprised of the following 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 the following 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 Catheters and the Symphony 16F 82cm Catheter target 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 in the peripheral vasculature or pulmonary anatomy. The 16F 82cm Catheter and compatible Dilator are introduced through a vascular access sheath into the peripheral vasculature and guided over a guidewire to the site of thrombus in the peripheral vasculature. The Symphony 16F 82cm Catheter and compatible Dilator are not intended for use in the pulmonary anatomy. Both the Symphony Catheters and the Symphony 16F 82cm Catheter are 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.

VI. COMPARISON WITH PREDICATE DEVICES

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

Table 1 provides a comparison of the subject Symphony Thrombectomy System and the subject Symphony 16F 82cm Thrombectomy System, and the predicate Symphony Thrombectomy System and the Symphony 16F 82cm Thrombectomy System.

Table 1: Summary Comparison between the Subject and Predicate Systems

	Predicate Devices	Subject Devices
Name of Device	Symphony Thrombectomy System Symphony 16F 82cm Thrombectomy System	Same
Manufacturer	Imperative Care, Inc.	Same
510(k) #	K250775	K252057
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 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.	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 and for the treatment of pulmonary embolism. Same for the Symphony 16F 82cm Thrombectomy System.
Product Code	QEW (Primary) KRA	Same
Regulation Name/Number	21 CFR 870.5150 Embolectomy Catheters	Same

	Predicate Devices	Subject Devices
Prescription/ Over-the-Counter Use	Prescription Only	Same
Single Use Only	Yes	Same
Catheter Design	Single-Lumen Intravascular Catheter	Same
Catheter Dimensions (OD, Length)	Symphony Thrombectomy System: 16F, 121 cm 24F, 85 Symphony 16F 82cm Thrombectomy System: 16F, 86 cm	Same
Thrombus Removal Assist Device	Over-the-Wire	Same
Packaged Accessories	Dilator, Symphony Clot Container	Same
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: 7 months Symphony Dilators: 7 months Symphony ProHelix: 25 months	Symphony Catheters: 13 months Symphony Dilators: 13 months Symphony ProHelix: Same

VII. PERFORMANCE DATA

The following verification tests were leveraged from the prior predicate Symphony Thrombectomy System (K223216) for the subject Symphony Thrombectomy System.

- Visual and Dimensional Verification
- Actuation Force Verification
- Tensile Strength Verification
- Positive Pressure/ Fluid Leak Verification
- Negative Pressure/ Air Leak Verification
- Burst Pressure Verification
- Catheter Intra-Shaft Bond Strength
- Corrosion Resistance Testing
- Coating Lubricity/Durability
- Drop Testing Verification
- Component Fatigue Testing Verification
- Fluoroscopy Validation (Visibility test)

For the Symphony Thrombectomy System, the following testing was conducted to support the expanded pulmonary embolism indication:

- Kink Radius
- Catheter Torque Strength
- Lumen Integrity
- Simulated Use Performance Validation
- Particulate Testing
- Coating Integrity

The 16F 82cm Symphony Thrombectomy System remains identical to the predicate 16F 82cm Symphony Thrombectomy System (K250775). No new performance testing was conducted for this device.

The in-vitro bench tests demonstrated that the subject Symphony Thrombectomy System met all acceptance criteria. Performance data demonstrate that the subject device functions as intended and the indications for use for treatment of pulmonary embolism for the subject Symphony Thrombectomy System does not raise any new questions of safety and/or effectiveness.

VIII. BIOCOMPATIBILITY

Biocompatibility of the subject Symphony Thrombectomy System and Symphony 16F 82cm Thrombectomy System patient-contacting components was assessed and testing was provided under prior 510(k) submission (K223216). Adherence to the test methodology and standards was maintained in the biocompatibility testing and the results met acceptance criteria. All testing was conducted in compliance with GLP regulations, 21 CFR Part 58. No additional biocompatibility tests were required and were appropriately leveraged from the predicate devices.

IX. 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 subject Symphony Thrombectomy System for treatment of pulmonary embolism. 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 question of safety or effectiveness for the Symphony Thrombectomy System in all measured assessments and supported treatment of the device for pulmonary embolism.

X. 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”.

XI. 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. New test methods and protocols were generated for verification tests specific to treatment of pulmonary embolism for the Symphony Thrombectomy System at T=0 and an accelerated aged time point.

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.

XII. CLINICAL STUDY

Introduction

The SYMPHONY-PE clinical study was a prospective, multicenter, single-arm, open label study. Its primary objective was to evaluate the safety and effectiveness of the Symphony Thrombectomy System in patients diagnosed with acute pulmonary embolism (PE). The study enrolled 109 subjects across 19 sites in the U.S. All 109 subjects were site-assessed as meeting all study inclusion and exclusion criteria, underwent the procedure, and were enrolled in the study (ITT cohort). A subset of 106 subjects from the full ITT cohort, in whom the study device was the only thrombectomy device used to treat the index PE and who did not require thrombolytics or other devices within 48 hours of the procedure, comprised the mITT cohort. An independent imaging core lab and a clinical events committee (CEC) reviewed safety endpoints data.

Study Design

Subjects between the age of 18 to 80 years old with clinical symptoms consistent with pulmonary embolism with an RV/LV greater than 0.9 as evidenced by CT angiography and assessed by investigators prior to procedure were recruited.

The primary efficacy endpoint was the independent core-lab adjudicated mean reduction in RV/LV from baseline to 48-hours post-procedure assessed by CT Angiography (CTA). A pre-specified performance goal for success was defined as achieving a lower one-sided 97.5% confidence interval (CI) bound >0.20. The primary safety endpoint was the rate of major adverse events defined as a composite rate of all-cause major bleeding, device-related mortality and device-related serious adverse events including clinical deterioration, pulmonary vascular injury, or cardiac injury assessed at 48-hours and adjudicated by an Independent Safety Board (ISB). A pre-specified performance goal for success was defined as achieving an upper one-sided 97.5% CI bound <15.0%.

Study Results

Primary and secondary safety endpoints were analyzed using the ITT population (n=109). The primary efficacy endpoint was analyzed using the modified intent to treat (mITT) population (N=106), excluding subjects who received thrombolytics or other adjunctive therapies within 48 hours. Of the 106 subjects in the mITT population, 102 subjects had paired baseline and 48-hour RV/LV measurements adjudicated by the core-lab and were included in the primary analysis (N=102).

The primary efficacy endpoint was the mean reduction in RV/LV between baseline and 48 hours post-procedure, as assessed by the independent imaging core-lab using CTA (**Table 2**). The mean reduction in RV/LV was 0.44 with a lower one-sided 97.5% confidence bound of 0.36 and

a p-value <0.001, demonstrating the pre-specified performance goal of >0.20 for the lower confidence bound was met by a wide margin.

Table 2: Primary Efficacy Endpoint Results

Endpoint	Mean RV/LV Reduction, Mean ± SD	Lower One-Sided 97.5% CI for Mean	Performance Goal for CI	p-value
Primary Analysis Mean Reduction in RV/LV Between Baseline and 48-Hours	0.44 ± 0.42	0.36	>0.20	<0.001

The primary safety endpoint was adjudicated by the Independent Safety Board (ISB) and was the 48-hour Major Adverse Events (MAE) rate, a composite of all-cause major bleeding within 48-hours, device-related death within 48-hours and device-related SAEs within 48-hours (including clinical deterioration, pulmonary vascular injury and cardiac injury).

The observed 48-hour MAE rate was 0.9% (1/109) with an upper one-sided 97.5% confidence bound of 5.7% and a p-value <0.001, demonstrating the pre-specified performance goal of <15.0% for the upper confidence bound was met by a wide margin (**Table 3**).

Table 3: Primary Safety Analysis Results

Endpoint	MAE Rate, % (n/N)	Upper One-Sided 97.5% CI	Performance Goal for CI %	p-value
Composite 48-Hour MAE Rate	0.9 (1/109)	5.7	<15.0	<0.001

Secondary safety endpoints included mortality which occurred in 0.0% at both 48-hours (0/109) and 30-day follow-up (0/108). The rate of device-related SAEs (clinical deterioration, pulmonary injury, or cardiac injury) was 0.0% (0/109). Symptomatic PE recurrence occurred in 2.8% (3/106) of subjects and was associated with concomitant DVT in all three (3) cases, with DVT identified as the likely source of the recurrent PE in two (2) subjects (**Table 4**).

Table 4: Secondary Safety Endpoints

Endpoint	Rate, % (n/N)	95% CI
ISB Adjudicated Major Bleeding		
VARC-2 Life Threatening or Disabling Bleed	0.0 (0/109)	<0.1 – 3.3
VARC-2 Major Bleeding	0.9 (1/109)	<0.1 – 5.0
48-Hour Device-Related Mortality	0.0 (0/109)	<0.1 – 3.3
48-Hour Device-Related Clinical Deterioration	0.0 (0/109)	<0.1 – 3.3
48-Hour Device-Related Pulmonary Vascular Injury	0.0 (0/109)	<0.1 – 3.3
48-Hour Device-Related Cardiac Injury	0.0 (0/109)	<0.1 – 3.3
30-Day Pulmonary Embolism Related Mortality	0.0 (0/108)	<0.1 – 3.4
30-Day All-Cause Mortality	0.0 (0/108)	<0.1 – 3.4
30-Day Device Related Serious Adverse Events	0.0 (0/106)	<0.1 – 3.4
30-Day Symptomatic PE Recurrence	2.8 (3/106)	0.6 – 8.0

In total, 11% (12/109) of subjects experienced at least one serious adverse event through the last completed follow-up.

Catheter Size Sub-Group Analysis:
There were no notable differences between the 16F Symphony catheter (used in 44 subjects) and the 24F Symphony catheter (used in 101 subjects). Both sized devices were used together in 36 procedures, and the analyzed sub-groups were not mutually exclusive. While the study was not powered to independently test the primary efficacy and safety endpoints in the catheter size sub-groups, the pre-specified performance goals were met in both the 24F and 16F sub-groups.

Conclusion
The SYMPHONY-PE clinical study demonstrated that the Symphony Thrombectomy System showed substantially equivalent safety and effectiveness outcomes for acute PE. The primary efficacy and safety endpoints were met.

XIII. CONCLUSIONS

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 were evaluated for applicability and either the rationale for no impact was documented or verification and validation 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 product codes, basic

technological characteristics such as components, design, materials, sterilization method, and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended.

Based on the non-clinical, pre-clinical, and clinical data presented above, the subject and predicate devices are substantially equivalent and there are no new questions of safety and/or effectiveness.