November 1, 2021

Volcano AtheroMed Inc.
Anna Stephen
Regulatory Operations Specialist
1530 O'Brien Drive, Suite A
Menlo Park, California 94025

Re: K193197
Trade/Device Name: QuickClear Mechanical Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Anna Stephen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 20, 2020. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.11.01 15:10:59 -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

April 20, 2020

Volcano AtheroMed Inc.
Ms. Anna Gloria Stephen
Regulatory Operations Specialist
1530 O'Brien Drive, Suite A
Menlo Park, California 94025

Re: K193197
Trade/Device Name: QuickClear Mechanical Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: March 20, 2020
Received: March 23, 2020

Dear Ms. Stephen:

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: 2020.04.20 17:03:43 -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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193197

Device Name
QuickClear Mechanical Thrombectomy System

Indications for Use *(Describe)*
The QuickClear Mechanical Thrombectomy System is intended for removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

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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*PRAStaff@fda.hhs.gov*

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# 5 510(k) Summary

This 510(k) Summary was prepared in accordance with 21 CFR 807.92 (c)

**Submitter Information:**

**Date of 510(k) Summary Preparation:** April 20, 2020

**Name and Address of Manufacturer:** Volcano AtheroMed, Inc.
1530 O'Brien Drive, Suite A
Menlo Park, CA 94025

**Establishment Registration Number:** 3008847191

**Contact Person:** Anna Gloria Stephen
Phone: (612) 666-3260
Fax: (916) 638-8812
Email: annagloria.stephen@philips.com

**Subject Device Information:**

| | |
|---|---|
| **Device Trade Name**: | QuickClear Mechanical Thrombectomy System |
| **Common Name:** | Aspiration System |
| **Regulation Description:** | Embolectomy Catheter |
| **Regulation Number:** | 21 CFR 870.5150 |
| **Product Code:** | DXE |
| **Device Class:** | Class II |
| **Classification Panel:** | Cardiovascular |

**Predicate Device:**

**Primary:** Penumbra INDIGO Aspiration System
510(k) Number: K180939, DXE, 870.5150

**Reference:** Teleflex Pronto .035" Extraction Catheter
510(k) Number: K070403, DXE, 870.5150 serves as a reference predicate with similar indications for use and the same catheter size (10F).

**Reference:** Phoenix 2.4 mm Atherectomy Plus System
510(k) Number: K181877, MCW, 870.4875 serves as a reference predicate for the QuickClear Aspiration Pump that was cleared as the Phoenix Aspiration Pump in K181877.

**Intended Use/ Indication for Use:**

The QuickClear Mechanical Thrombectomy System is intended for removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

**Device Description:**

The QuickClear Mechanical Thrombectomy System is an aspiration thrombectomy system designed for removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. The QuickClear Mechanical Thrombectomy System removes thrombus from the peripheral vasculature using continuous vacuum aspiration, through a single lumen aspiration catheter. The system components are sterile, single-use devices that are sterilized using Ethylene Oxide (EO). The QuickClear Mechanical Thrombectomy System comprises the following devices and accessories:

- **QuickClear Aspiration Pump:** The QuickClear Aspiration Pump is identical to the previously cleared Phoenix Aspiration Pump that is part of the Phoenix 2.4 Atherectomy *Plus* System (K181877) and remains unchanged as part of the QuickClear Mechanical Thrombectomy System. The pump is sterile, single-use, battery-operated, has an ON/OFF button, and serves as a vacuum source for aspirating thrombus from target vessel/s out of the QuickClear Aspiration Catheter via the pump aspiration tubing into a waste collection bag (connected to the pump outlet). Aspiration is controlled via an inline flow control switch. The aspiration pump is non-patient contacting.

    - **A 60cc Syringe** assists in priming the pump tubing and purging the aspiration system of air. The syringe can also be used to provide additional vacuum by pulling the plunger during active aspiration. The 60cc Syringe is provided with the Aspiration Pump Kit

- **QuickClear Aspiration Catheters:** Catheters are available in the following sizes: 6F straight tip, 8F straight tip, 8F shaped tip and 10F shaped tip. The QuickClear Aspiration Catheters continuously aspirate and remove thrombus and emboli from the vasculature when connected to the QuickClear Aspiration Pump. The catheters have a marker band tip for enhanced fluoroscopic visualization and are hydrophilic-coated to enhance lubricity. A Hemostasis Valve Y-connector is supplied with the catheter and connects to the proximal catheter hub. The QuickClear Aspiration Pump tubing is attached to the Hemostasis Valve Y-connector port to provide vacuum to the catheter for removal of thrombus.
    - **An Obturator** is supplied with the 8F and 10F catheters. The Obturator is intended to be used as an over-the-wire (OTW) accessory, positioned within the lumen of the catheter, for tracking over commercially available 0.035” guidewires. The Obturator provides catheter support and atraumatic advancement through the vasculature during catheter placement.

- **A Waste Collection Bag** is connected to the proximal end of the aspiration pump tubing to collect aspirated material.

**Comparison with Predicate**:

The QuickClear Mechanical Thrombectomy System has been assessed for substantial equivalence relative to the currently marketed Penumbra INDIGO Aspiration System (K180939) as the predicate device, along with consideration of two additional reference devices, the Phoenix 2.4mm Atherectomy *Plus* System (K181877) and the Teleflex Pronto .035" Extraction Catheter (K070403). The indications for use for QuickClear Mechanical Thrombectomy System are similar to the indications for use of the predicate device Penumbra INDIGO Aspiration System. The QuickClear System and the INDIGO System have similar **technological characteristics** and **operating principles.** Both devices consist of two main components Aspiration Catheter and Aspiration Pump. The pump provides continuous vacuum through the single-lumen catheter for the removal of fresh, soft emboli and thrombi from the peripheral vasculature.

The basic operating principle of the Pronto Extraction Catheteris similar to the QuickClear 10F Aspiration Catheter. The Pronto .035" Extraction Catheter serves as a reference predicate with similar indications for use and technological characteristics based on the 10F catheter size to compare with the 10F subject catheter size targeting safe thrombus removal from the larger diameter venous and arterial vessels. Both catheters are designed to be delivered through a 10F or larger introducer sheath over a 0.035" guidewire.

Additionally, the Phoenix 2.4 mm Atherectomy Plus System serves as a direct reference predicate since the QuickClear Aspiration Pump is identical to the Phoenix Aspiration Pump cleared in K181877.

Any differences between the subject and predicate device were evaluated through technological comparison (also taking into account the noted reference devices), design verification and validation testing to demonstrate that the subject QuickClear Mechanical Thrombectomy System is substantially equivalent to the currently marketed predicate device..

Some of the similarities and differences between the subject device and the predicate devices are outlined in **Table 5-1** below

| Table 5-1:Comparative Summary of QuickClear Mechanical Thrombectomy System and Predicate Devices | | | | |
|---|---|---|---|---|
| **Attribute** | **Subject Device** | **Predicate Device** | **Reference Device** | **Direct Reference Device** |
| ***Trade Name (510(k) #)*** | **QuickClear Mechanical Thrombectomy System (K193197)** | **Penumbra INDIGO Aspiration System (K180939)** | **Teleflex Pronto .035" Extraction Catheter (M20650400) (K070403)** | **Philips Volcano AtheroMed Phoenix 2.4mm Atherectomy Plus System (K181877)** |
| ***Classification*** | Class II, DXE | Class II, DXE | Class II, DXE | Class II, MCW |
| ***Regulation Description*** | Embolectomy Catheter | Embolectomy Catheter | Embolectomy Catheter | Catheter, Peripheral, Atherectomy |
| ***Regulation Number*** | 870.5150 – Embolectomy Catheter | 870.5150 – Embolectomy Catheter | 870.5150 – Embolectomy Catheter | 870.4875, Intraluminal Artery Stripper |
| ***Classification Panel*** | Cardiovascular | Cardiovascular | Cardiovascular | Cardiovascular |
| ***Indications For Use*** | The QuickClear Mechanical Thrombectomy System is intended for removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. | INDIGO Aspiration Catheters and Separators:<br>As part of the INDIGO Aspiration System, the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.<br><br>INDIGO Aspiration Tubing:<br>As part of the INDIGO Aspiration System, the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Aspiration Pump.<br><br>Penumbra Aspiration Pump: The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems. | The Pronto .035"extraction catheter is indicated for:<br>• The removal/aspiration of embolic material (Thrombus/Debris) from vessels of the arterial system.<br>• The removal/aspiration of embolic material (Thrombus/Debris) from vessels of the deep venous system.<br>• To infuse/deliver diagnostic or therapeutic agents. | The Phoenix Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The system is not intended for use in the coronary, carotid, iliac, pulmonary, or renal vasculature.<br><br>Phoenix Atherectomy Plus System:<br><br>When used with the Phoenix Aspiration Pump as the vacuum source, the Phoenix 2.4 Deflecting Atherectomy System is indicated for the removal of thrombus from vessels of the peripheral arterial vasculature. |
| ***Thrombus Collection and Removal*** | Continuous aspiration and removal of emboli and thrombus via a vacuum aspiration source with the | Continuous aspiration and removal of emboli and thrombus via a vacuum aspiration source with the catheter targeted at | Removal of emboli and thrombus mechanically via a 60 cc syringe based aspiration through the extension line and | Continuous collection and removal of emboli and thrombus via mechanical conveyance of |

| Table 5-1:Comparative Summary of QuickClear Mechanical Thrombectomy System and Predicate Devices | | | | |
|---|---|---|---|---|
| **Attribute** | **Subject Device** | **Predicate Device** | **Reference Device** | **Direct Reference Device** |
| ***Trade Name (510(k) #)*** | **QuickClear Mechanical Thrombectomy System (K193197)** | **Penumbra INDIGO Aspiration System (K180939)** | **Teleflex Pronto .035" Extraction Catheter (M20650400) (K070403)** | **Philips Volcano AtheroMed Phoenix 2.4mm Atherectomy Plus System (K181877)** |
| | catheter targeted at thrombus in the peripheral vasculature. | thrombus in the peripheral vasculature. | stopcock source with the catheter targeted at thrombus in the peripheral vasculature. | Catheter assisted by a vacuum aspiration source. |
| ***Basic Operating Principle/ General Technological Design*** | Continuous aspiration and removal of emboli and thrombus via a vacuum aspiration source with the catheter targeted at thrombus in the peripheral vasculature.<br><br>The aspiration catheter accesses the thrombotic occlusions within the vasculature and is used to aspirate material directly through the catheter lumen. The catheter is introduced over a guidewire (0.035") to the site of the target occlusion to perform aspiration when connected to the aspiration pump that serves as a vacuum source. An obturator, supplied with the catheter (8F & 10F only), may be used to facilitate access through the vessel while providing an atraumatic transition to the front edge of the catheter. The catheter connects to the distal end of a vacuum pump through hemostasis and inline ON/OFF valve. The male luer on the exit port of the vacuum pump tubing connects to the female luer | Continuous aspiration and removal of emboli and thrombus via a vacuum aspiration source with the catheter targeted at thrombus in the peripheral vasculature.<br><br>The aspiration catheter accesses the thrombotic occlusions within the vasculature and is used to aspirate material directly through the catheter lumen.<br>The catheter is introduced over a guidewire (0.035") to the site of the target occlusion to perform aspiration when connected to the aspiration pump that serves as a vacuum source.<br><br>A separator may be deployed within the Aspiration Catheter to assist with thrombus removal by clearing the lumen of the Aspiration Catheter should it become blocked with thrombus. The separator is manually advanced and retracted through the Aspiration Catheter at the proximal margin of the primary occlusion to facilitate clearing of the thrombus from the Aspiration Catheter tip.<br><br>A separator may not be necessary when using an Aspiration Catheter with an ID of 0.054" (4Fr) or larger. | The Pronto .035" extraction catheter is a dual lumen, over-the-wire (OTW) catheter with related accessories. The catheter is designed to be delivered through a 10F or larger introducer sheath over a 0.035" guidewire. The larger lumen allows for the removal of thrombus by use of the included syringe through the extension line and stopcock. The catheter has a rounded distal tip with a protected, extraction lumen to facilitate advancement of the catheter into the blood vessel and maximize extraction of thrombus through the extraction lumen.<br><br>The catheter has a radiopaque marker band located approximately 4mm from the distal tip. The proximal end of the catheter incorporates a hemostatic Y-junction that allows for the attachment of the catheter to the included extension line, stopcock and syringe; and can be tightened down on the guidewire to prevent blood leakage. | Phoenix Aspiration System Pump - handheld<br>battery powered pump<br>capable of providing a<br>vacuum source of ≥ 25inches<br>Mercury (Hg) to aspirate<br>blood and thrombus related<br>materials. |

| | | | | |
|---|---|---|---|---|
| | on the waste collection bag tubing.<br><br>Aspirated material is collected in a waste collection bag.<br><br>Aspiration Pump - handheld battery powered pump capable of providing a vacuum source of ≥ 25inch Mercury (Hg) to aspirate blood and thrombus related materials. | Aspirated material is collected in a suction canister. | | |
| ***Power Source*** | 12V DC Battery for Aspiration Pump | 100-115V AC/230V AC, 50/60 HZ AC Power supply for Penumbra Max Pump | N/A (manual aspiration) | 12V DC Battery for Phoenix Aspiration System Pump |
| ***Vacuum Source*** | ≥ 25 inch Hg Vacuum | Up to 29 inch Hg Vacuum (electrical, piston vacuum pump) | 60 ml Syringe with locking plunger located on the extension line. | ≥ 25 inch Hg Vacuum |
| ***Syringe Accessory*** | 60cc Syringe | N/A | 60cc syringe | 60cc Syringe |
| ***Waste Collection Source*** | 1400ml Waste Collection Bag | 1200ml Waste Collection Canister | 60cc Syringe | 1400ml Waste Collection Bag |
| **Aspiration Catheter** | | | | |
| ***Aspiration Catheter Outer Diameters*** | 6F=0.081"<br>8F= 0.107"<br>10F=0.130" | 6F= 0.079"<br>8F=0.105" | 10F=0.128" | N/A |
| ***Tip Shape Configurations*** | 6F - Straight<br>8F - Straight<br>8F – Shaped<br>10F – Shaped | 6F - Straight<br>8F - Straight<br>8F - Shaped | 10F – rounded tip | N/A |
| ***Catheter Working Lengths*** | 6F= 130 cm<br>8F= 85 cm<br>10F= 85 cm | 6F= 135 cm<br>8F= 85 cm | 10F = 115 cm | N/A |
| ***Target Vessel Diameters*** | 6F: > 3.0 mm<br>8F: > 4.0 mm<br>10F: > 5.0 mm | 6F: > 4.0 mm<br>8F: > 4.0 mm | 10F: > 4.0 mm | N/A |
| ***Guidewire Compatibility*** | .035” | .035” | .035” | N/A |
| ***Obturator Outer Diameter*** | 8F = 0.084 – 0.088”<br>10F= 0.104 – 0.108” | N/A | N/A | N/A |

| | | | | |
|---|---|---|---|---|
| **Aspiration Tubing** | | | | |
| ***Tubing Inner Diameter (ID)*** | 0.100 – 0.125” | 0.071” – 0.110” | N/A | N/A |
| **General** | | | | |
| ***Materials*** | Polymeric blends commonly utilized for interventional devices | Polymeric blends commonly utilized for interventional devices | Polymeric blends commonly utilized for interventional devices | N/A |
| ***Catheter Coating*** | Yes | Yes | No | N/A |
| ***Biocompatibility*** | Per ISO 10993-1 | Per ISO 10993-1 | Per ISO 10993-1 | N/A pump is non patient contacting |
| ***Packaging Configuration*** | Catheters and pump are Individually packaged in Tyvek Pouch and chipboard boxes | Catheters are Individually packaged in Tyvek Pouch and chipboard boxes | Catheters are Individually packaged in Tyvek Pouch and chipboard boxes | Pump is individually packaged in Tyvek Pouch and chipboard boxes |
| ***Sterilization*** | Ethylene Oxide (EO)<br>All components | Ethylene Oxide (EO)<br>(Catheter/separator) | Ethylene Oxide (EO) | Ethylene Oxide (EO) |
| ***Single Use Only*** | Catheter: Yes<br>Aspiration Pump: Yes | Catheter/separator : Yes<br>Vacuum Pump :<br>(reusable/electrical) | Catheter : Yes | Catheter: Yes<br>Aspiration Pump: Yes |

**Testing Summary**:

Since there is no change to the currently marketed Phoenix Aspiration Pump that is used as part of the subject QuickClear Mechanical Thrombectomy System (K181877), previous testing for biocompatibility, bench performance, sterilization, packaging and shelf-life, electrical safety and EMC, remain applicable and was not repeated.

To demonstrate the substantial equivalence of the subject QuickClear Mechanical Thrombectomy System to the selected predicate device, the performance and technological characteristics were evaluated by completion of the following tests:

- **Aspiration Catheter Tests:**
  - Catheter Visual Inspection
  - Catheter Dimensional Inspection
  - Catheter Dry Leak Test
  - Catheter Vacuum Test
  - Catheter Flow Rate Test
  - Catheter Tensile Test
  - Catheter Torque Strength Test
  - Catheter Lubricity Test

- **Quick QuickClear Mechanical Thrombectomy System Test:**
  - QuickClear Mechanical Thrombectomy System Simulated Use Test

- **Aspiration Catheter and Obturator Tes**t:
  - Guidewire Compatibility Test for Aspiration Catheter and Obturator
  - Kink Resistance Test for Aspiration Catheter and Obturator

- **Obturator Test (8F and 10F Aspiration Catheter Only):**
  - Obturator Visual Inspection
  - Obturator Dimensional Inspection

- QuickClear vs. Predicate System Comparative Test
- Sterilization Validation
- Packaging and Shelf Life Tests

- **Biocompatibility Tests:**
  The following biocompatibility tests were conducted on the QuickClear Aspiration Catheters and Obturators per ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process:
    - Cytotoxicity
    - Sensitization
    - Irritation or Intracutaneous Reactivity

- Acute Systemic Toxicity
- Partial Thromboplastin Time (PTT)
- Material-Mediated Pyrogenicity
- Hemocompatibility
- Particulate Analysis
- *In vivo* Thrombogenicity

The QuickClear Aspiration Pump is a non-patient contacting device, and therefore, biocompatibility testing was not required or conducted on the Aspiration Pump.

- **Preclinical Animal Testing:**
  A GLP animal study was conducted to evaluate the safety and performance of the QuickClear Mechanical Thrombectomy System in an animal model. The study concluded:
  - No vessel trauma
  - No evidence of side effects
  - Minimal to no vascular injury

**Conclusion**

The subject QuickClear Mechanical Thrombectomy System shares the same intended use, technological characteristics, and principles of operation with the currently marketed predicate and reference devices. The QuickClear Pump is identical to the currently cleared reference Phoenix Aspiration Pump that is part of the Phoenix 2.4 Atherectomy *Plus* System (K181877). The QuickClear Aspiration catheters are similar in design and construction as the predicate Penumbra Indigo Catheters. Any differences between the subject and predicate devices were evaluated through design verification and validation testing to demonstrate that the subject QuickClear Mechanical Thrombectomy System is substantially equivalent to the currently marketed predicate device.

Based on the information submitted in this 510(k) premarket notification, the subject QuickClear Mechanical Thrombectomy System is substantially equivalent to the currently marketed predicate Penumbra INDIGO Aspiration System.