June 24, 2026

Insera Therapeutics, Inc.
% Lina Kontos
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth St. NW,
Washingon, DC 20004 USA

Re: K253404
Trade/Device Name: CLEAR™ Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: May 22, 2026
Received: May 22, 2026

Dear Lina Kontos:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

KRINA M. PATEL -S

Digitally signed by KRINA M. PATEL -S
Date: 2026.06.24 16:26:23 -04'00'

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)*
K253404

Device Name

CLEAR™ Aspiration System

Indications for Use *(Describe)*

The CLEAR Aspiration System is intended for the 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.

510(k) Summary

Contact Details

Applicant Name: Insera Therapeutics, Inc.
Applicant Address: 5546 Serrano Ave, Dallas, TX 75248, USA
Applicant Contact Telephone: +1 (646) 270-3531
Applicant Contact: Vallabh Janardhan, MD, FAHA
Applicant Contact Email: vallabh@inseratherapeutics.com
Date prepared: June 24, 2026

Device Name

Device Trade Name: CLEAR™ Aspiration System
Common Name: Embolectomy catheter
Classification Name: Peripheral Mechanical Thrombectomy With Aspiration
Regulation Number: 870.5150
Product Code(s): QEZ (Class II)

Legally Marketed Predicate Devices

The legally marketed predicate device and reference devices of the subject device, CLEAR™ Aspiration System, are identified in **Table A** below.

Table A - List of Predicate and Reference Devices for the CLEAR™ Aspiration System

510k Number	Name of Device	Name of Manufacturer
Predicate Device		
K142870	Predicate for Pump and Entire Aspiration System: Penumbra Embolectomy Aspiration System (Indigo® Aspiration System)	Penumbra, Inc.
Reference Devices		
K192981	Reference for Aspiration Catheter & System: Indigo® Aspiration System - Aspiration Catheter 12 and Separator 12	Penumbra, Inc.
K180939	Reference for Aspiration Tubing & System: Indigo Aspiration System® with modified 110 Aspiration Tubing	Penumbra, Inc.

Indications for Use

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

Device Description Summary

The CLEAR™ Aspiration System is designed to remove thrombus from the vasculature using mechanical aspiration. The CLEAR™ Aspiration System is comprised of several compatible components, working together to achieve the intended use:

- INSERA™ Canister and Non-sterile (intermediate) Tubing
- CLEAR™ Aspiration Pump
- INSERA™ Aspiration Tubing
- INSERA™ Catheter

The CLEAR Aspiration Pump, the INSERA Canister, plus the Non-sterile (intermediate) Tubing are provided non-sterile and are used outside the sterile field. The canister and the non-sterile (intermediate) tubing come pre-assembled, are single-use and function as a repository for aspirated material. The INSERA Canister is placed into the receptacle of the CLEAR Aspiration Pump while the Non-sterile Tubing is connected to the vacuum inlet port, located on the top of the pump.

Placement of the INSERA Catheter is achieved through over-the-wire introduction through a guide catheter or vascular sheath, followed by the advancement of the catheter, over a guidewire, to the target vessel. Once the desired location has been reached, the guidewire is removed, and the procedure can commence. The INSERA Catheter is used with the CLEAR Aspiration Pump to aspirate thrombus from an occluded vessel. The CLEAR™ Aspiration System supports several presets suction levels: Cyclical, Uniform, and Saver.

Predicate Comparison

The CLEAR™ Aspiration System is substantially equivalent to the claimed predicate device; Penumbra Embolectomy Aspiration System (Indigo® Aspiration System) (K142870) based on comparisons of the intended use and technological characteristics.

Table B - Comparison Table of Subject Device to Predicate Device

Attributes	CLEAR™ Aspiration System (Subject Device)	Indigo® Aspiration System (K142870) (Predicate Device)
Regulation #	21 CFR Part 870.5150	21 CFR Part 870.5150
Regulation Name	Embolectomy Catheter	Embolectomy Catheter
Regulatory Class	II	II

Product Code	QEZ	DXE
Indications for Use	The CLEAR Aspiration System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.	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.
Aspiration Pump (Non-Sterile)		
Control Panel/ Display	Digital	Analog
Vacuum Range	0 -29 inHg (98.2 kPa)	0 -29 inHg (98.2 kPa)
Flow Rate	Flow Rate 2.0 – 2.3 SCFM (0-60.9 LPM)	Flow Rate 0-0.8 SCFM (0-23 LPM)
Temperature	Operating: 18◦C - 24◦C (65◦F - 75◦F)	Operating: 18◦C - 24◦C (65◦F - 75◦F)
Relative Humidity (RH)	Operating: 10% - 85% (<85% RH)	Operating: <75% RH
Pressure	Operating: 81kPa at Sea Level – 1828.8 meters (6000 feet); Range 70kPa – 105kPa	Operating: 81kPa at Sea Level – 1828.8 meters (6000 feet); Range 70kPa – 105kPa
Voltage	115Vac/230Vac	100-115Vac (Model PMX110) 230Vac (Model PMX220)
Frequency	50 Hz/60 Hz	50 Hz/60 Hz
Duty Cycle	Non-continuous 75% (90 mins on, 30 mins off)	Non-continuous 97.8% (45 mins on, 1 min off)
IEC 60601-1 Compliance	Yes	Yes
IEC 60601-1-2 Compliance	Yes	Yes
Collection Canister and Intermediate Tubing (Non-Sterile)		
Components (Materials)	1,200ml Setup: INSERA Collection Canister (1,200ml) & (Non-sterile Tubing) Intermediate Tubing	1,000ml Setup: Indigo™ Collection Canister (1,000ml) & (Non-sterile Tubing) Intermediate Tubing Filter
Volume	1,200ml	1,000ml
Use	Single use, disposable	Single use, disposable
Aspiration Tubing (Sterile)		
Materials	Biocompatible, commonly utilized for interventional devices.	Biocompatible, commonly utilized for interventional devices.
Dimensions	Usable Length = 100.0” Inner Diameter =	Usable Length = 112.0” Inner Diameter =

	0.110” Outer Diameter = 0.188” Distal length = N/A (Single Construction)	0.110” Outer Diameter = 0.188” Distal length = 7.0”
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)
Use	Single use, disposable	Single use, disposable
Aspiration Catheter (Sterile)		
Materials	Biocompatible, commonly utilized for interventional devices.	Biocompatible, commonly utilized for interventional devices.
Coating	Hydrophillic	Hydrophillic
Dimensions	SAME plus larger diameters	Appropriately sized for the target vessel
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)

Performance Data

The following non-clinical performance bench tests were conducted for the CLEAR™ Aspiration System:

- **Design verification testing**
  - Catheter
    - dimensional verification
    - suction pressure
    - flow rate
    - catheter/guidewire compatibility
    - coating integrity and particulate evaluation
    - lumen burst pressure
    - tensile strength
    - elongation
    - corrosion resistance
  - Aspiration tubing
    - Dimensional/Visual Inspection
    - Suction Connector /Canister Lid (Luer/Port) Compatibility
    - Rotating Luer/RHV (Luer/Port) Compatibility
    - Aspiration Tubing Lumen Ovalization under Vacuum
    - Aspiration Tubing Joint Leak under Vacuum
  - Pump
    - Flow Control (Digital) Switch Function
    - Aspiration System Compatibility with Aspiration Tubing
    - Suction Connector / Tubing Joint Tensile Strength
    - Rotating Male Luer / Tubing Joint Tensile Strength
- **Durability test** to determine the number of hours of continuous operation of the CLEAR™ Aspiration System
- **Usability test** to evaluate the usability, kink resistance, trackability, and performance attributes of the CLEAR™ Aspiration System compared to predicate device; Indigo®

Aspiration System.

- **Electromagnetic Compatibility (EMC) test** in compliance with IEC 60601-1-2
- **Electrical Safety test** in compliance with IEC 60601-1
- **ISO 10079-1** compliance assessment
- **Packaging Validation test**
- **Software Validation and Cybersecurity**
- **Sterilization Validation** in accordance with ISO 11138
- **Shelf Life Tests**: Package integrity tests in accordance with ISTA 3A and shelf life validation in accordance with ASTM F1980.
- **Biocompatibility**: Biocompatibility studies were selected in accordance with ISO 10993-1 as summarized in the table below:

Table C – List of biocompatibility tests

Test	Relevant Standards	Test Result
INSERA Aspiration Tubing		
MEM Elution	ISO 10993-5 ISO 10993-12	Pass
Maximization Test for Delayed-Type Hypersensitivity	ISO 10993-10 ISO 10993-12	Pass
Intracutaneous Reactivity Test	ISO 10993-23 ISO 10993-12	Pass
In-vivo Thrombogenicity	ISO 10993-4	Pass
INSERA Catheter		
MEM Elution	ISO 10993-5 ISO 10993-12	Pass
Maximization Test for Delayed-Type Hypersensitivity	ISO 10993-10 ISO 10993-12	Pass
Intracutaneous Reactivity Test	ISO 10993-23 ISO 10993-12	Pass
Acute System Toxicity Test	ISO 10993-11 ISO 10993-12	Pass
Rabbit Pyrogen-Material Mediated	ISO 10993-11 ISO 10993-12	Pass
Hemolysis ASTM	ASTM F756-17 ISO 10993-12	Pass
Complement Activation Assay C3a and CS5-9	ISO 10093-12 ISO 10993-1 ISO 10993-4	Pass

Animal Study

An animal study was conducted to evaluate the safe use of the CLEAR™ Aspiration System including the CLEAR™ Aspiration Pump, INSERA™ Catheters, INSERA™ Aspiration Tubing, and INSERA™ Canister and Non-sterile Tubing compared to the predicate device namely Penumbra's Indigo® Aspiration System and showed that the in-vivo safety profile was similar between the subject and predicate devices at both the acute and chronic time points. The studies concluded that:

- No vessel injury was noted on the final angiograms following the vessel response procedure.
- No abnormal gross or significant histology findings were noted in the test vessel segments. If any, these findings did not affect vascular integrity and were less than or similar to the control (predicate) device.
- The use of the devices resulted in no significant vascular response in these experimental conditions.

Conclusion

Insera Therapeutics, Inc. believes that the subject device: CLEAR™ Aspiration System, is substantially equivalent to the claimed primary predicate device: Penumbra's Indigo® Aspiration System (K142870), based on comparisons of the intended use and technological characteristics. While some technological characteristic differences exist between the subject device and the primary predicate device, the differences do not raise different questions of safety or effectiveness. Reference devices support the use of the catheter, pump, and aspiration system together. Further, non-clinical performance data confirm that these differences do not raise any additional risks. Additionally, the performance data demonstrates that the subject device is substantially equivalent to the legally marketed primary predicate device.

The CLEAR™ Aspiration System therefore meets the Federal Food, Drug and Cosmetic Act criteria for 510(k) clearance of this device.