December 18th 2025

Endovascular Engineering, Inc.
Debra Cogan
VP, Clinical & Regulatory Affairs
3925 Bohannon Drive
Suite 300
Menlo Park, California 94025

Re: K252956
Trade/Device Name: Helo Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: November 24, 2025
Received: November 25, 2025

Dear Debra Cogan:

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,

Shelby Buffington -S

Digitally signed by Shelby Buffington -S
Date: 2025.12.18 15:45:50 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252956

Device Name
Hēlo Thrombectomy System

Indications for Use *(Describe)*
The Hēlo Thrombectomy System is indicated for:
• The non-surgical removal of emboli and thrombi from pulmonary arteries and venous vasculature.
• The system allows for injection, infusion, and/or aspiration of contrast media and other fluids into or from blood vessels.

The Hēlo Thrombectomy System is intended for use in the peripheral veins and for the treatment of pulmonary embolism.

The Hēlo Audible Flow Indicator is intended for use exclusively with the Hēlo Thrombectomy System and provides audible feedback of rapid flow through the device during a thrombectomy procedure.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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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
for the
Hēlo Thrombectomy System

I. SUBMITTER

Name:	Endovascular Engineering
Address:	3925 Bohannon Drive, Suite 300 Menlo Park, CA 94025, USA
Contact:	Debra Cogan, VP Regulatory & Clinical
Telephone:	408-515-0820
Email:	dcogan@e2helo.com

Date Prepared:	December 16, 2025

II. DEVICE

Name of Device:	Hēlo™ Thrombectomy System
Common or Usual Name:	Thrombectomy Catheter
Classification Name:	Peripheral Mechanical Thrombectomy with Aspiration
Regulatory Class:	II
Regulation Number:	21 CFR 870.5150
Product Code:	QEW (primary), KRA

III. PREDICATE DEVICE

Primary Predicate Device:	Penumbra Indigo Aspiration System - Lightning Flash (K222358)
Reference Predicate Device:	Endovascular Engineering Hēlo™ G1 Thrombectomy System (K223891)

IV. DEVICE DESCRIPTION

The Hēlo Thrombectomy System (Hēlo System) is a minimally invasive aspiration system designed for the removal of thromboembolic material from the pulmonary arteries. It can be initially introduced with a 16 Fr introducer sheath and expands to 8 mm at the distal portion once inside the vasculature. The Hēlo System allows for engagement with the targeted clot, aspiration of the targeted clot, and transportation of aspirated clot out of the body. The Hēlo System is supplied sterile using Ethylene Oxide gas and is intended for single-use only. The Hēlo System is comprised of the following components:

- Aspiration Catheter: The Aspiration Catheter includes a funnel, an outer sleeve, and an integrated handle with controls. The handle also features a side port for the purposes of fluid injection, flushing of the inner lumen of the Aspiration Catheter, and for measurement

of intravascular pressure using a standard pressure line setup, if needed. A second side port is used to purge air from the outer sleeve prior to use. The Aspiration Catheter is compatible with a 0.035" or 0.038" guidewire. It connects to a commercially available vacuum pump.

- Agitator: The Agitator is intended to be inserted in the inner lumen of the Aspiration Catheter. It includes a drive unit that connects to the proximal end of the Aspiration Catheter. The Agitator is designed to mechanically disrupt emboli within the distal region of the Aspiration Catheter during aspiration. The Agitator may be disconnected, removed, and reintroduced through the Aspiration Catheter during use.

- Rotating Hemostatic Valve (RHV): The RHV is an accessory that can be attached to the proximal end of the Aspiration Catheter when the Agitator is removed from the Aspiration Catheter. The RHV includes a Tuohy Borst valve to enable compatibility and sealing on ancillary devices, such as guidewires.

- 9F Dilator: The 9F diameter, Dilator is an accessory that is compatible with 0.035" or 0.038" guidewires and can be used to facilitate navigation through the heart.

- Audible Flow Indicator (AFI): The AFI is an optional accessory that connects between the suction port of the aspiration handle and the suction canister and provides audible feedback to the operator when actuation of the Suction/Agitator Control Button results in full flow through the device. A clot catcher made up of a coarse filter attaches to the suction canister and provides visualization of the clot.

V. INDICATIONS FOR USE

The Hēlo Thrombectomy System is indicated for:

- The non-surgical removal of emboli and thrombi from pulmonary arteries and venous vasculature.
- The system allows for injection, infusion, and/or aspiration of contrast media and other fluids into or from blood vessels.

The Hēlo Thrombectomy System is intended for use in the peripheral veins and for the treatment of pulmonary embolism.

The Hēlo Audible Flow Indicator is intended for use exclusively with the Hēlo Thrombectomy System and provides audible feedback of rapid flow through the device during a thrombectomy procedure.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Hēlo System incorporates similar design features, procedural steps, and performance characteristics when compared to the primary and reference predicate devices. All 3 devices are single-use, disposable, catheter-based technologies that are provided sterile by EO. Like both predicate devices, the Hēlo System is delivered over a guidewire to the target clot and has a similar clinically relevant working length. Both the Hēlo System and primary predicate are indicated for the removal of thrombus and emboli from pulmonary arteries. Both the Hēlo System and the reference predicate provide for the delivery and removal of fluids from vessels such as delivery of heparinized

saline, contrast medium and other fluids through a side-port. The Hēlo System and both predicates utilize a vacuum pump for direct extraction of clot.

Characteristic	Subject Device	Primary Predicate	Reference Predicate
Name and 510(k) #	Hēlo Thrombectomy System	Indigo Aspiration System - Lightning Flash	Hēlo™ G1 Thrombectomy System
510(k)#	K252956	K222358	K223891
Manufacturer	Endovascular Engineering, Inc.	Penumbra, Inc.	Endovascular Engineering, Inc.
Classification	Class II, QEW, KRA	Class II, QEW	Class II, QEW, KRA
Intended Use	Emboli and thrombus removal	Emboli and thrombus removal	Emboli and thrombus removal
Guidewire compatibility	0.035" - 0.038"	0.014" - 0.038"	0.035" - 0.038"
Guidewire access	OTW	OTW	OTW
Dilator included	Separate dilator packaged with device	No dilator	Separate dilator packaged with device
Outer diameter	16F	16F	16F
Catheter working length	95cm	80, 100, 115cm	95cm
Hydrophilic coating	Yes	Yes	Yes
Battery Voltage	6V	N/A	6V
Has a Rotating Hemostatic Valve	Yes	Yes	Yes
Contains an Agitator	Stainless Steel	N/A	Stainless Steel
Utilizes a vacuum pump?	Yes	Yes	Yes
Mechanism of Action	Mechanical removal and aspiration of thrombus using a vacuum pump for suction. The Agitator wire can be removed and wiped down to remove wrapped clot clogging the blocked thrombus. The AFI provides audible feedback to gauge procedure progress.	Removes thrombus from the vasculature using mechanical aspiration sourced from the Penumbra vacuum pump. The Indigo Separator may be used to clear the lumen of the aspiration catheter should it become blocked with thrombus. The Indigo Aspiration Tubing provides audible feedback to	Mechanical removal and aspiration of thrombus using a vacuum pump for suction. The Agitator wire can be removed and wiped down to remove wrapped clot clogging the blocked thrombus. The AFI provides audible feedback to gauge procedure progress.

Characteristic	Subject Device	Primary Predicate	Reference Predicate
		gauge procedure progress.	
Radiopacity	Visible under fluoroscopy	Visible under fluoroscopy	Visible under fluoroscopy
Angled tip to assist with navigation	Yes	Yes	Yes
Has audible indicator for blood flow?	Yes	Yes	Yes
How provided	Sterile, single use	Sterile, single use	Sterile, single use
Sterilization Method and packaging	EO sterilized. Single sterile barrier system with protective packaging outside.	EO sterilized. Single sterile barrier system with protective packaging outside.	EO sterilized. Single sterile barrier system with protective packaging outside.
Shelf life	12 months	36 months	9 months

VII. PERFORMANCE DATA

Bench studies indicate that the Hēlo System performs as intended. The testing was performed in conformance with design inputs and input from risk management, national and international standards, and FDA feedback. Testing included:

- Simulated Use
- Corrosion
- Clot Aspiration
- Radial Force
- Crush Force
- Vacuum
- Mechanical Heat Generation
- Tensile
- Torque
- Particulate

Sterilization Validation

Sterilization validation was performed on the Hēlo System in accordance with ISO 11135 and demonstrated a sterility assurance level of 10^{-6}.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO-10993-1 requirements. The results demonstrated no chemical, toxicological, or safety risks associated with the Hēlo System components, manufacturing processes, or sterilization method. The device is considered biocompatible for its intended use. Testing encompassed the following:

- Cytotoxicity
- Sensitization
- Acute systemic toxicity
- Material Mediated Pyrogenicity
- Intracutaneous Reactivity

- Hemolysis
- Complement Activation
- Thrombogenicity

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical Safety and EMC testing were conducted on the Hēlo System and demonstrated compliance with IEC 60601-1 and IEC 60601-2 standards.

Shelf-Life and Packaging
Accelerated aging testing per ASTM F1980 was conducted on the Hēlo System to verify the performance of the device, accessories, and packaging. Sterile barrier integrity was maintained following aging. Packaging integrity was confirmed after transportation testing. The following packaging integrity testing was performed:

- Visual Inspection for damage to shipper box, shelf cartons and labels
- Visual Inspection per ASTM F1886/1886M-16
- Gross Leak per ASTM F2096-11
- Seal Strength per ASTM F88-21

Animal Testing
The Hēlo System was subjected to GLP and non-GLP in-vivo animal testing that confirmed the device did not raise questions related to safe use.

VIII. CLINICAL DATA

Study Design
The ENGULF Study is a prospective, multicenter, single-arm, study evaluating the safety and effectiveness of the Hēlo System. Subjects between the age of 18 and 80 eligible for endovascular treatment of symptomatic acute submassive pulmonary embolism (PE), with an RV/LV ratio greater than 0.9 as evidenced by CT angiography and assessment by the investigator prior to the procedure, were recruited.

Study Results
Primary and secondary safety endpoints were analyzed using the ITT population (n=105). The primary effectiveness endpoint was analyzed using the modified intent to treat (mITT) population (N=100), excluding subjects who received thrombolytics or other adjunctive therapies within 48 hours. The primary effectiveness endpoint of this study was the RV/LV ratio change from baseline to 48 hours as assessed by CT angiography. The mean RV/LV ratio change from baseline to 48 hours post-procedure was compared to a pre-specified performance goal of 0.12 RV/LV ratio reduction. The mean reduction in RV/LV was 0.40 with a p-value <0.001, demonstrating the pre-specified performance goal of >0.12 was met by a wide margin.
The primary safety endpoint was the composite rate of device-related major adverse events defined as major bleeding, mortality and serious adverse events including clinical deterioration, pulmonary vascular injury, or cardiac injury assessed at 48-hours and adjudicated by an Independent Clinical Events Committee (CEC). The percentage of subjects that experience the composite safety endpoint was compared to a pre-specified performance goal of 25% for this endpoint. The observed 48-hour MAE rate was 1.9% (2/105: 1 probable/likely device relationship, 1 possible/unlikely) with a p-value <.001, demonstrating the pre-specified performance goal of <25.0% for the upper confidence bound was met by a wide margin.

Refer to the Instructions for Use for detailed clinical study results.

IX. CONCLUSIONS

The Hēlo System is substantially equivalent to the primary and reference predicates for intended use, principles of operation, technological characteristics, anatomical site, performance, and safety characteristics. Based on the performance, animal, and clinical testing it has been demonstrated that the Hēlo System performs as intended and does not raise any new questions of safety and effectiveness when compared with the predicate devices.