June 11, 2025

Medtronic, Ireland
Barbara Zampedri
Sr Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K250787
Trade/Device Name: Liberant Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: March 14, 2025
Received: March 14, 2025

Dear Barbara Zampedri:

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 ARIEL G. ASH-SHAKOOR -S
Date: 2025.06.11 09:39:35 -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)*
K250787

Device Name
Liberant Thrombectomy System

Indications for Use *(Describe)*
The Liberant Thrombectomy System is indicated for the removal of fresh, soft emboli or thrombi from the 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

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information

Applicant/ Submitter Name and Address	Medtronic Ireland Parkmore Business Park West Galway, Ireland
Contact Person	Barbara Zampedri Senior Regulatory Affairs Specialist Email: barbara.zampedri@medtronic.com
Date Prepared	June 06, 2025
Device Trade Name	Liberant™ Thrombectomy System

Subject Device

Device Classification	Regulatory Class: II
Classification Panel	Cardiovascular Coronary and Peripheral Interventional Devices
Classification Name	Peripheral Mechanical Thrombectomy with Aspiration
Regulation Number	21 CFR 870.5150
Product Code	QEW

Predicate Device

Device Trade name	Indigo Aspiration System
510(K) Number / Clearance Date	K142870 / May 26, 2015 K192981 / May 28, 2020 K193244 / March 13, 2020

Device Description

The Liberant Thrombectomy System consists of the Liberant Thrombectomy Set (catheter, clot-buster, dilator, aspiration tubing and hemostasis valve), Liberant Blood Conservation Unit (BCU), Riptide Aspiration Pump and Riptide Collection Canister with intermediate tubing. The Liberant Thrombectomy Set is single use and provided sterile.

The Liberant BCU and Riptide Pump are provided separately from the Liberant Thrombectomy Set as non-sterile capital units. The single use, non-sterile Riptide Collection Canister is provided separately to the pump.

Indications for Use

The Liberant Thrombectomy System is indicated for the removal of fresh, soft emboli or thrombi from the vessels of the peripheral arterial and venous systems.

Predicate Comparison

Attribute	Predicate Device	Subject Device
Trade Name	**Penumbra INDIGO Aspiration System**	**Liberant Thrombectomy System**
510(k) Number	K142870, K192981, K193244	K250787
Classification	Class II, QEW	Same
Regulation Number	870.5150 – Embolectomy Catheter	Same
Indications For Use	INDIGO Aspiration Catheters and Separators: 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. INDIGO Aspiration Tubing: 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.	The Liberant Thrombectomy System is indicated for the removal of fresh, soft emboli or thrombi from the vessels of the peripheral arterial and venous systems.

Attribute	Predicate Device	Subject Device
Trade Name	**Penumbra INDIGO Aspiration System**	**Liberant Thrombectomy System**
Basic Operating Principle/ General Technological Design	Continuous aspiration: Continuous aspiration and removal of emboli and thrombus via a vacuum aspiration source with the catheter targeted at thrombus in the peripheral vasculature. Access: 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. Fragmentation Tool: A separator, supplied separately, may be used to assist with thrombus removal and to clear the lumen of the catheter should it become blocked. In the event of catheter blockages, the separator can be inserted into the catheter lumen to disrupt the blockage.	Continuous aspiration: Same Access: Same Fragmentation Tool: A clotbuster, supplied with the catheter, may be used to assist with thrombus removal and to clear the lumen of the catheter should it become blocked. In the event of catheter blockages, the clotbuster can be inserted into the catheter lumen to disrupt the blockage.
Aspiration Catheter		
Sizes Available	6F 8F 12F	6F 8F 12F
Catheter Effective Lengths	6F: 135 cm 8F Short: 50cm 8F Long: 115cm 12F: 115cm	Same
Guidewire Compatibility	0.035"	Same
Clotbuster		
Length	SEP6: 175cm SEPD: 90cm SEP8: 150cm SEP12: 150cm	6F: 151cm 8F Short: 66cm 8F Long: 131cm 12F: 131cm
General		
Biocompatibility	Per ISO 10993-1	Same
Sterilization	Ethylene Oxide (EO)	Thrombectomy Set: Same BCU: non-sterile
Shelf Life	36 months	Thrombectomy Set: 6 months BCU operational lifetime: 500 hours

Summary of Non-Clinical Data

Medtronic performed design verification and validation testing to provide evidence to demonstrate substantial equivalence of the subject device to the predicate device. All data met the acceptance criteria and fell within pre-determined product specifications. The follow testing was performed:

Performance Testing:

- Dimensional/Visual Inspection
- Performance/Simulated Use Testing
- Tensile Testing
- Coating Integrity
- Aspiration Tubing compatibility
- Vacuum Testing
- Blockage & Flow detection
- Direct User Testing
- Human Factors & Usability Testing
- GLP animal study

Biocompatibility Evaluation:

- Cytotoxicity Colony Assay
- Systemic Toxicity Material Mediated Rabbit Pyrogen
- ISO Intracutaneous Irritation test
- In Vitro Skin Irritation Assay
- ISO Acute Systemic Toxicity Study
- ISO Maximisation Sensitisation in Guinea Pigs
- Haemocompatibility

Shelf-life
Sterilization
Packaging
Software Validation
Electrical and Electromagnetic compatibility testing

Conclusion

Non-clinical testing supports substantial equivalence of the subject device, Liberant Thrombectomy System, to the predicate device, Penumbra Indigo Aspiration System.