September 4, 2025

Microbot Medical Ltd.
Lina Kontos
Regulatory Counsel
Hogan Lovells
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K243789
Trade/Device Name: LIBERTY Endovascular Robotic System
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II
Product Code: DXX
Dated: August 5, 2025
Received: August 5, 2025

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 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,

LYDIA S. GLAW -S
Digitally signed by LYDIA S. GLAW -S
Date: 2025.09.04 17:39:03 -04'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
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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)*
K243789

Device Name
LIBERTY Endovascular Robotic System

Indications for Use *(Describe)*
The LIBERTY® Endovascular Robotic System is intended for use in the remote delivery and manipulation of guidewires and catheters, and remote manipulation of guide catheters, to facilitate navigation to anatomical targets in the peripheral vasculature.

The LIBERTY® Endovascular Robotic System is not intended for coronary or neurointerventional procedures.

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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510(k) Summary

Microbot Medical's LIBERTY® Endovascular Robotic System

Submitter Microbot Medical LTD
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Contact Person: Noa Ofer, PhD

Date Prepared: August 4, 2025

Name of Device: LIBERTY® Endovascular Robotic System

Common or Usual Name: LIBERTY® Endovascular Robotic System

Classification Name: System, Catheter Control, Steerable

Regulatory Class: Class II
21 CFR 870.1290

Product Code: DXX Steerable Catheter Control System

Predicate Device: Magellan
Device Class: II
Product Code: DXX
Regulation Number: 21 CFR 870.1290
510(k) Number: K151730

Reference device: CorPath GRX System
Device Class: II
Product Code: DXX
Regulation Number: 21 CFR 870.1290
510(k) Number: K173288

Device Description

The LIBERTY® Endovascular Robotic System (LIBERTY System) is a single-use, sterile, disposable device designed to help physicians navigate guidewires and catheters in peripheral endovascular procedures. It allows physicians to control the devices remotely using a handheld controller while enabling a physician to remain seated and away from the X-ray radiation source, thus reducing radiation exposure.

Key components:

- Bedside Robotic Drive: This motorized unit grips and maneuvers the interventional devices.

- Handheld Remote Control: This wireless controller allows the physician to remotely advance, retract, and rotate the guidewire and microcatheter by communicating with the Robotic Drive.
- Mounting Arm: This arm securely attaches the Robotic Drive to the patient's bed near the insertion point.
- Accessories: These include hemostatic valves and an extension tube for managing fluids during the procedure.

The system is intended to be used in peripheral endovascular procedures. Following manual insertion of an introducer sheath and guide catheter, the system is utilized via the handheld remote control that operates the robotic drive from a distance and enables remote positioning of guidewire and catheter (microcatheter) devices at a desired point inside the peripheral vasculature. Once the interventional devices are placed at the target site using the LIBERTY Robotic System, the devices are used manually consistent with their cleared indications for use for the interventional procedure.

Intended Use / Indications for Use

The LIBERTY® Endovascular Robotic System is intended for use in the remote delivery and manipulation of guidewires and catheters, and remote manipulation of guide catheters, to facilitate navigation to anatomical targets in the peripheral vasculature.

The LIBERTY® Endovascular Robotic System is not intended for coronary or neurointerventional procedures.

Summary of Technological Characteristics

Both the LIBERTY system and the cleared predicate, the Magellan Robotic System (K151730), include the same core components in the form of a robotic drive, a user console powered by software, and a mounting arm. They are designed to manipulate vascular interventional devices using software-operated motors, and they allow independent control of guidewire and catheter advancement while enabling the physician to sit away from the radiation source.

The LIBERTY system in relation to its predicate device has a more compact and portable design that is intended for single-use; being fully sterile, and disposable; is controlled through a handheld, wireless remote controller instead of a wired console; and utilizes a mechanical mounting arm. Nevertheless, these minor differences do not raise different questions of safety or effectiveness, as explained further below.

It is maintained that while the LIBERTY system has some technological differences from its predicate, these differences do not raise different question of safety or effectiveness. The CorPath GRX K173288 reference device also drives a guidewire and a catheter using similar mechanical principles and is intended for use for remote manipulation of catheters and guidewires. The LIBERTY system has been thoroughly tested and validated through standardized evaluations to address the substantially equivalent safety and effectiveness profile.

	LIBERTY® Endovascular Robotic System Subject Device	Magellan (K151730, K111004) Predicate Device	SE Discussion
Manufacturer	Microbot Medical, Inc.	Hansen Medical, Inc.	-
Regulation Class	Class II	Class II	Same
Product Code	DXX (Steerable catheter control system)	DXX (Steerable catheter control system)	Same
Regulation Number	21 CFR 870.1290	21 CFR 870.1290	Same
Intended Use/ Indications for Use	The LIBERTY® Robotic System is intended for use in the remote delivery and manipulation of guidewires and catheters, and remote manipulation of guide catheters to facilitate navigation to anatomical targets in the vasculature. The LIBERTY® Robotic System is not intended for coronary or neurointerventional procedures.	The Hansen Medical Magellan Robotic System and accessory components are intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices. The Magellan Robotic System is intended to be used with compatible Hansen Medical robotically steerable catheters.	Substantially the same – all systems are intended for use with interventional surgical devices for their remote navigation and placement at the target site. Both the subject and the predicate device are intended to provide access for manual use of interventional devices at the same target anatomical locations.
User Population	Physicians specialized in endovascular procedures.	Physicians specialized in endovascular procedures.	Same
Device Components	• Robotic Drive • Remote controller (Bluetooth) • Articulated Arm	• Workstation • Remote controller • Set up joint (articulated arm) • Bedside Electronics Module • Bedside Controller • Electronics Rack	Substantially the same – all systems include robotic drives mounted on articulated arms, being remotely controlled through a remote controller/ console.
Operational Principles	The physician manipulates guidewires, catheters and guide catheters using joysticks	The physician, seated at the Remote Workspace, manipulates guidewires and Magellan Robotic	Substantially the same

	LIBERTY® Endovascular Robotic System Subject Device	Magellan (K151730, K111004) Predicate Device	SE Discussion
	or controls on the remote controller.	catheters using joysticks or touchscreen controls on the Control Console.	
Linear Movement of Endovascular Devices	Yes, allows for linear movement of: • Guidewire • Microcatheter • Guide catheter (fine adjustments)	Yes, allows for linear movement of: • Guidewire • Magellan Robotic Catheter	Substantially the same – all allow for linear movement of compatible surgical interventional devices
Rotational Movement of Endovascular Devices	Yes – for the Guidewire and Guide catheter	Yes, for: • Guidewire • Magellan Robotic Catheter	Substantially the same – all allow for rotational movement of compatible devices
Mechanical Control System	Master/Slave control system with servo motor/encoder and Bluetooth interface	Master/Slave control system with servo motor/encoder and cable interface	Substantially the same – differences in communication are accounted for in bench testing
Safety Features	E-stop button, Abort button on the remote controller, Quick switch to manual interface	E-stop button, Quick switch to manual interface	Substantially the same

Performance Data

The Company executed its V&V plan which covered the following areas:

- Specification and performance verification including force and torque verification, flow testing, coating integrity, interventional device compatibility testing, linear and rotational speed velocity, emergency stop verification
- Biocompatibility
- Sterilization validation
- Environmental testing (Transportation and Shelf-life validation)
- EMC, Electrical Safety, and wireless coexistence
- Software validation
- Cybersecurity testing and documentation
- Human Factors Usability Validation Study
- GLP certified pre-clinical animal study
- Clinical study

All testing passed successfully.

Human Factors Usability Study

A Human Factors (HF) Validation Study for the Product was conducted in a simulated-use environment, including participants representing the Product's two user groups: Physicians and Assistants.

All critical tasks required to use the Product were assessed. During the study, participants were engaged in simulated-use scenarios where they were presented with the Product and asked to perform tasks representative of how they would interact with the Product in real life. The company performed a detailed assessment of all use errors, close calls, and use difficulties observed in the HF validation study, together with their root cause analysis. An assessment was made of each use event's possible clinical impact, possible mitigations, and finally the acceptability of remaining risk following any mitigation. All identified residual risks were of non-critical severity, and the assessment found these risks to be acceptable.

GLP-Certified Pre-Clinical Animal Study

The Company conducted a GLP-certified pre-clinical animal study with the aims to evaluate the safety, usability and performance of the LIBERTY® Endovascular Robotic System to manipulate a range of guidewires and catheters for use in peripheral percutaneous vascular procedures in comparison to the manual standard care of method (manual control).

Six animals underwent robotic intervention, and three animals underwent control (manual) intervention, targeting a total of 8 target sites per animal in the peripheral area.

All study objectives were met. Nine animals were enrolled into the study and completed the study per protocol. No major events such as death, artery perforation, or thrombosis occurred during any interventional procedure. There were no clinically relevant sign or symptoms throughout the follow-up period in relation to the test article or control intervention.

Clinical Study

The company conducted a prospective, multi-center, single-arm, study to evaluate the performance and safety of the LIBERTY® Endovascular Robotic System in human subjects undergoing Peripheral Vascular Interventions, including 20 participants in three US-based sites.

Successful robotic navigation of the guidewire and microcatheter was defined as reaching at least 95% of the predetermined anatomical target locations using the LIBERTY® Endovascular Robotic System, without switching from a robotic to manual procedure due to difficulty reaching the target site. All 20 enrolled subjects underwent successful navigation to the target locations. The success rate was 100% (20/20) success.

No serious adverse events, no serious adverse device effects, no unanticipated adverse device effects, no unanticipated adverse device effects, and no reportable adverse events.

Conclusions

The LIBERTY® Endovascular Robotic System is substantially equivalent to the predicate. The LIBERTY® system has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device.

In addition, the technological differences between the LIBERTY® system and its predicate device raise no different questions of safety or effectiveness. Performance data demonstrate that the LIBERTY® system is substantially equivalent to the predicate, Magellan system.