September 30, 2025

Distalmotion, SA
% Lina Kontos
Regulatory Counsel
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K251197
Trade/Device Name: Dexter L6 System
Regulation Number: 21 CFR 878.4965
Regulation Name: Electromechanical surgical system with transient sterile field presence of both surgeon and primary control interface
Regulatory Class: Class II
Product Code: SDD
Dated: September 25, 2025
Received: September 25, 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 and the October 25, 2024 De Novo classification order for

this device type. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Per the October 25, 2024 De Novo classification order for this device type, you must demonstrate that the device performs as intended under anticipated conditions of use in the intended patient population and anatomical location. The special control requirements set forth in that order include initiation, enrollment, completion, and reporting requirements associated with any required postmarket surveillance. Within 30 days of receipt of this letter, you must submit a complete study protocol for a postmarket surveillance study consistent with the special control requirements. FDA expects to work with you to approve your study protocols within 60 days of this letter. Your submission should be clearly labeled as "Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the 510(k) number above to facilitate processing. If there are multiple protocols being finalized after clearance of this 510(k) submission, please submit each protocol as a separate submission, identified by their unique study name(s).

From the date of study protocol approval, you must meet the following timelines:

- First subject enrolled within 12 months
- 20% of subjects enrolled within 24 months
- 50% of subjects enrolled within 36 months
- 100% of subjects enrolled within 48 months

In addition, you must submit separate periodic reports on the progress of the study as follows:

- Postmarket surveillance progress reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the protocol approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting enrollment status reports every three (3) months in addition to your annual postmarket study progress reports, until enrollment has been completed, or FDA notifies you otherwise.
- Submit the final postmarket study report three (3) months from study completion (i.e., last subject's last follow-up date).

Each postmarket surveillance report should be submitted to the Agency as specified below, identified as a "Postmarket Surveillance Report" in accordance with how the study is identified above, and bearing the applicable 510(k) reference number.

Be advised that failure to comply with any special control requirement, including the initiation, enrollment, completion, and reporting per the postmarket surveillance data requirements outlined above, may result in the adulteration and misbranding of your device.

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).

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above 510(k) number to facilitate processing.

Postmarket Mandated Studies Program
U.S. Food and Drug Administration
Center for Devices and Radiological Health

Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Alternatively, documents can be submitted electronically through the CDRH Portal. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2025.09.30 14:13:00 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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.

Submission Number *(if known)*

K251197

Device Name

Dexter L6 System

Indications for Use *(Describe)*

The Distalmotion Dexter L6 System is intended to assist in the accurate control of endoscopes as well as endoscopic instruments for endoscopic manipulation of tissue, including grasping, suturing, dissecting, coagulating and cutting, with or without high frequency functionality. The Distalmotion Dexter L6 System is intended for use in laparoscopic inguinal hernia repair, cholecystectomy and total benign hysterectomy including salpingo-oophorectomy. The system is indicated for adult use, defined as 22 years old and older. It is intended for use by trained laparoscopic or robotic surgeons in an operating room environment in accordance with the representative and specific procedures set forth in the Instructions for Use.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

DISTALMOTION DEXTER L6 SYSTEM

Submitter: Distalmotion SA
Route de la Corniche 3b
1066 Epalinges
Switzerland

Contact: Larry Carrier
VP Regulatory Affairs
Phone: +1-707-239-6086
Email: larry.carrier@distalmotion.com

Date Prepared: April 17, 2025

Trade/Device Name: Dexter L6 System

Regulation Number: 21 CFR 878.4965

Regulation Name: Electromechanical surgical system with transient sterile field presence of both surgeon and primary control interface

Regulatory Class: Class II

Product Code: SDD

Review Panel: General & Plastic Surgery

Predicate Devices: Dexter L6 System (DEN230084)

Device Description:

The Dexter L6 System is designed to enable complex surgery using a minimally invasive approach. It is composed of the Robot, the single-use accessories, fully articulated instruments, as well as reusable accessories.

The Robot consists of a Surgeon Console, with which the surgeon controls the movement of the instruments and of the Endoscope Arm using two Handle Grips (reusable), a Clutching Foot Pedal and an Endoscope Foot Pedal; two Patient Carts positioned at the operating room table in which the instruments are inserted and removed through the Hub during surgery; and the Dexter L6 Software installed in the Robot firmware.

The single-use, sterile instruments consist of the Needle Holder, Bipolar Johann Grasper, Bipolar Maryland Dissector, Monopolar Scissors, and Monopolar Hook.

The single-use accessories consist of the Sterile Interface, Endoscope Arm and Sterile Drapes.

The reusable accessories consist of the Accessory tray, Incision Pointer, Emergency Release Tool and Handle Grips.

Intended Use / Indications for Use:

The Distalmotion Dexter L6 System is intended to assist in the accurate control of endoscopes as well as endoscopic instruments for endoscopic manipulation of tissue, including grasping, suturing, dissecting, coagulating and cutting, with or without high frequency functionality. The Distalmotion Dexter L6 System is intended for use in laparoscopic inguinal hernia repair, cholecystectomy and total benign hysterectomy including salpingo-oophorectomy. The system is indicated for adult use, defined as 22 years old and older. It is intended for use by trained laparoscopic or robotic surgeons in an operating room environment in accordance with the representative and specific procedures set forth in the Instructions for Use.

The Dexter L6 System is for prescription use only.

Summary of Technological Characteristics:

The subject device has similar technological characteristics as the predicate device, the Dexter L6 System (DEN230084). The design changes to the Dexter L6 System components (robot including software, instruments, reusable accessories) do not raise different questions of safety and effectiveness. Performance data to support these changes demonstrates that the subject device is safe and effective as the predicate device.

Performance Testing:

Bench Testing

Extensive bench testing was conducted on the subject Dexter L6 System to verify effective implementation of the design changes. The following tests confirmed that the modified Dexter L6 System performs as intended and meets its predetermined performance specifications:

- System testing, encompassing: Motion Replication, Endoscope Control, Safe-state and Emergency Stop, Protective Stop, Collision Management, Release of Patient and Human-device interface;
- Accuracy and Precision;
- Workspace access;
- System set-up;
- Performance testing with compatible devices;
- Sub-system testing, encompassing for the Surgeon Console: Functional Tests, Mechanical Rigidity and Resistance, Mechanical Balance and Motion Smoothness, Motion Capture and Sensor Resolution, Workspace Mechanical and Electrical Reliability;

- Sub-system testing, encompassing for the Patient Carts: Functional Tests, Mechanical Rigidity and Resistance, Motion Smoothness, Workspace, Mechanical and Electrical Reliability;
- Instruments, encompassing for the five instrument types: Functional Tests, Mechanical Rigidity and Resistance, Mechanical and Electrical Reliability, Micro Workspace;
- Accessories, encompassing specific tests for Sterile Interface, Endoscope Cart, and the Sterile Drapes.
- Prior testing to evaluate the thermal effects on tissue by the electrosurgical functionalities of the bipolar and monopolar instruments.

Reusable Accessories Reprocessing Validation

A reprocessing validation study was conducted to confirm the overall effectiveness of the prescribed cleaning and steam sterilization procedures for the additional number of use cycles. The end-of-life validation test results demonstrated that the reusable accessories allow them to be effectively reprocessed and functional according to the reprocessing instructions provided in the labeling.

Instruments Shelf-Life Testing

A new shelf-life validation was conducted to support the instruments shelf-life extension from 1 year to 18 months.

Instruments Sterilization Validation

A revalidation of the Ethylene Oxide sterilization process for the modified instruments was conducted to demonstrate that the Sterility Assurance Level (SAL) of at least 10^{-6} is maintained.

Biocompatibility Testing

Additional cytotoxicity tests were successfully conducted to support the biocompatibility safety profile of the modified instruments.
The biocompatibility of the Incision Pointer (reusable accessory) was tested after the extended use lifetime, and the non-cytotoxic profile of the device was effectively demonstrated.

Software Testing

Extensive software testing was conducted to demonstrate that the subject Dexter L6 System continues to reliably operate as designed with all implemented software changes.

Electrical Safety and Electromagnetic Compatibility Testing

Additional electrical safety testing and electromagnetic compatibility tests were conducted on the modified Dexter L6 System, which demonstrated that the system still complies with current versions of IEC 60601-1 (Basic safety and essential performance), IEC 60601-1-2 (Electromagnetic disturbances), IEC 60601-2-2 (High frequency surgical accessories), and IEC 80601-2-77 (Robotically assisted surgical equipment).

Human Factors Testing

Human factors validation studies were conducted with the final instructions for use and training materials to evaluate the critical tasks related to the Dexter L6 System design changes, and to support the benign hysterectomy indication expansion. These human factors validation tests, guided by a

thorough use related risk analysis, have resulted in a product that facilitates user tasks and mitigates risks associated with use errors that could lead to serious harm.

Clinical Data

The HYPER Study was a prospective, multicenter, open-label, clinical investigation to confirm the perioperative and early postoperative safety and effectiveness of the Dexter L6 System in patients undergoing robotic-assisted laparoscopic hysterectomy with adnexal surgery for benign disease.

The HYPER Study included 52 subjects who were enrolled and on whom robotic-assisted surgery with Dexter was at least started (mITT population). The most important parameter used to measure the performance of a robotic surgical system is the conversion to an alternative procedure.

The primary performance endpoint, defined as successful completion of the Dexter-assisted procedure without conversion to an open or fully laparoscopic surgical approach, was confirmed in 52 out of 52 procedures (100%). No conversions to open surgery were recorded in the Dexter study. These results demonstrate that Dexter performs as intended in robotic-assisted laparoscopic hysterectomy.

The main safety parameter used to determine the clinical safety of robotic surgical systems is the major complication rate defined as Clavien-Dindo grades III – V. One major complication (Clavien-Dindo grade III-V) occurred in the study population operated with Dexter, representing a major complication rate of 2%. This demonstrates that Dexter is safe when used as intended in robotic-assisted laparoscopic hysterectomies.

The high procedural success rate and low occurrence of postoperative (Clavien-Dindo grades III-V) adverse events up to 42 days confirm the perioperative and early postoperative safety and clinical performance (efficacy) of the Dexter Robotic System in subjects undergoing robotic-assisted laparoscopic hysterectomy.

In conclusion, the results of the HYPER Study demonstrate the Dexter L6 System is safe and effective for subjects undergoing benign hysterectomies.

Conclusions:

The subject Dexter L6 System and the predicate Dexter L6 System (DEN230084) have the same intended use, similar indications for use and similar technological characteristics. The expanded indications for use do not change the intended use of the device and the different technological characteristics (design changes) do not raise new or different questions of safety and effectiveness.

The clinical performance of the device with benign hysterectomy procedures indicate that no new issues of safety or effectiveness are raised for the expanded indications.

Thus, the subject Dexter L6 System is substantially equivalent to the predicate device.