May 27, 2025

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

Re: K250435
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: February 14, 2025
Received: April 17, 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2025.05.27 13:16:59 -04'00'

Mark Trumbore Ph.D.
Assistant Director
DHT4A: Division of General Surgery 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.

Submission Number *(if known)*

K250435

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 and cholecystectomy. 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.

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510(K) SUMMARY

DISTALMOTION DEXTER L6 SYSTEM

Submitter: Distalmotion SA
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Date Prepared: May 23, 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 Dexter L6 System is compatible with standard single-use laparoscopic trocars measuring 10 [mm] in diameter and larger.

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 and cholecystectomy. 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.

The indications for use statement are consistent with the previously cleared Dexter L6 system, except for the additional of the term “suturing” to the statement and the addition of use of the system in performing cholecystectomy procedures.

Summary of Technological Characteristics:

The subject device has the same technological characteristics as the predicate device, the Dexter L6 System (DEN230084). The labeling has been changed to address use of the device in cholecystectomy procedures, to clarify the contraindications and that the device can be used for suturing.

Performance Data:

There have been no changes to the device since the previous clearance (DEN230084), other than the modification to expand the indications for use to include cholecystectomy indication. Extensive bench testing was conducted on the previously cleared Dexter L6 System, and these data remain applicable to support the safety and effectiveness of the subject device.

Clinical Data:

The NEST (DEXTER-assisted Non-Emergent and acute cholecystectomy) Study was a prospective, multicenter, open-label, clinical investigation to confirm the perioperative and early postoperative safety and effectiveness of the Dexter Robotic System (Dexter) in patients undergoing cholecystectomy.

The NEST Study included 51 subjects who were enrolled and on whom robotic-assisted surgery with Dexter was at least started (mITT population). Subject data was collected at baseline, intraoperatively, discharge, and postoperatively at 30 days.

The mean age of the mITT population was 55.1 years. Female subjects accounted for 62.7% (32/51). Most subjects were classified as ASA II status 84.3% (43/51). A demographic and comorbidity comparison of the NEST cohort and the EU and US literature is included in the table below.

Demographic/ Comorbidity	NEST (n=51)	EU Literature	US Literature	Discussion
Age (years)	55.1 ± 14.7	42.1-80	44.3-61.1	NEST cohort in range
Gender	64.2% (Female)	71-76.6 (Female)	55-77% Female	NEST cohort in range
Ethnicity	58.8% (White) 2% (African American) 3.9% (Other) 35.3% (Unknown or Not Reported)	Not reported	53.7-89.2 (White) 4-14.7% (African American) 0.4-21.2 (Hispanic)	NEST cohort in range for most common White ethnicity NOTE: Due to patient privacy regulations in France, the reported ethnicity of 35.3% (Unknown/ Not Reported) also includes additional subjects with White ethnicity.
BMI (kg/m²)	27.7	23.4-29	28.8-35.6	NEST cohort similar to US population. See Obesity comorbidity below.
ASA Status	92% (ASA I/II) 7.8% (ASA III+)	63 - 97% (ASA I/II) 3-37% (ASA III+)	54.4 - 80.2% (ASA I/II) 19.7-54.6% (ASA III+)	NEST cohort higher proportion of ASA I/II EU population and US population in similar range
Nassar Difficulty Scale Rating	21.6% (I) 45.1% (II) 27.5% (III) 5.9% (IV)	Not reported	Not reported	Nassar Scale only reported for NEST cohort
Obesity (> 30 kg/m²)	21.6% (n=11/51)	Not reported	5.7-54.2%	NEST cohort in range of US population
Hypertension	25.5% (13/51)	Not reported	27-59.7%	NEST cohort similar to US population
COPD	Not reported	8.4%	2.05-8.8%	EU population in range of US population
Cardiac Disease	23.5% (N=12/51)*	6.4%	0.2-17.3	EU population in range of US population
Diabetes	13.7 (7/51)	4.3-20.1%	9.2-24.4%	NEST cohort in range of US population
Hypothyroidism	5.8% (3.51)	Not reported	Not reported	Hypothyroidism only reported for NEST cohort
Smoking	Not reported	9-35%	13.1-28.9%	EU population in range of US population

The operation was successfully performed in 50 out of 51 subjects of the mITT population using robotic-assisted surgery (98.0%, 50/51), (95% CI:89.6%, 100.0%).

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 50 of 51 procedures from the mITT group (98.0%). One subject was converted to laparoscopic mode due to time constraints in which the surgeon decided to complete the procedure laparoscopically to shorten the operative time.

For the primary safety endpoint, there was one postoperative (Clavien-Dindo grades III-V) adverse

event perioperatively up to 30 days. There were 10 adverse events and two serious adverse events in the perioperative phase to 30 days after the procedure.

Two serious adverse events were reported (4.0%):

- Post-operative agranulocytosis and pancytopenia as an adverse reaction to metamizole therapy. The event was resolved at the time of study completion and classified as Clavien-Dindo II, not related to the procedure and not related to the device.
- Re-hospitalization due to the migration of a pre-existing choledocholithiasis. The event was resolved at the time of study completion and classified as Clavien-Dindo III, not related to the procedure and not related to the device.

Two intraoperative adverse events were reported (4.0%):

- Gallbladder perforation; the event was treated with prophylactic antibiotics. The event was resolved at the time of study completion and was classified as Clavien-Dindo II, procedure related and not related to the device.
- Injury of the posterior wall of the gallbladder; the event was treated with prophylactic antibiotics. The event was resolved at the time of study completion and was classified as Clavien-Dindo II, procedure related and not related to the device.

None of the subjects required reoperation after the index procedure. In conclusion, the results of the NEST Study demonstrate the Dexter L6 System is safe and effective for subjects undergoing cholecystectomy.

Conclusions:

The subject Dexter L6 System is as safe and effective as the predicate device. The subject Dexter L6 System has the same intended uses and similar indications, same technological characteristics, and principles of operation as its predicate device. The expanded specific indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Analysis and clinical performance data of the device with cholecystectomy procedures demonstrate that the Dexter L6 System is as safe and effective as the predicate device. Thus, the subject Dexter L6 System is substantially equivalent.