



August 11, 2026

Distalmotion SA
Coline Lahaye
Regulatory Affairs Specialist
Rte. De La Corniche 3b
Epalinges, VD 1066
Switzerland

Re: K261398

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: July 9, 2026

Received: July 9, 2026

Dear Coline Lahaye:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.08.11
13:00:51 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261398

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Please provide the device trade name(s).

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Dexter L6 System

Please provide your Indications for Use below.

?

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 and ventral hernia repair, cholecystectomy, total benign hysterectomy including salpingo-oophorectomy and sacrocolpopexy. 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.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(K) SUMMARY

DISTALMOTION DEXTER L6 SYSTEM

Submitter: Distalmotion SA
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1066 Epalinges
Switzerland

Contact: Coline Lahaye
Regulatory Affairs Specialist
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Email: regulatory@distalmotion.com

Date Prepared: April 30, 2026

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 (K251197)

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 and ventral 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 (K251197). The labeling has been changed to address use of the device in ventral hernia repair procedures.

Performance Data:

There have been no changes to the device since the previous clearance (K251197), other than the modification to expand the indications for use to include ventral hernia repair indication. Extensive bench testing was conducted on the previously cleared Dexter L6 System, and the testing data remain applicable to support the safety and effectiveness of the subject device.

Clinical Data:

The RAVEN (Robotic minimally invasive Ventral HErNia repair with Dexter ®) Study was a post-market, 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 ventral hernia repair.

The mITT population, defined as patients who were enrolled and on whom robotic-assisted surgery with Dexter was at least started, included 33 subjects. All subjects were followed for 30 days postoperatively.

The mean age of the mITT population (N=33) was 56.5 ± 14.5 years. The mean BMI was 27 kg/m², with 27.3% patients classified as class I obese (9/33). The primary indication for surgery was symptomatic hernia, reported in 84.8% of patients (28/33). Additional indications included cosmetic

concerns in 27.3% of patients (9/33), painful bulge in 9.1% (3/33), enlarged hernia in 6.1% (2/33), and bowel obstruction in 3.0% (1/33).

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 32 out of 33 procedures (97.1%). No conversions to open surgery were recorded in the study.

For the primary safety endpoint, there was one (3.0%) Clavien-Dindo grades III-V event perioperatively up to 30 days in one subject with bleeding (Grade IIIa). The event was assessed as procedure-related and resulted in a hospitalization of five days. Resolution was confirmed by the 30-day follow-up visit.

None of the subjects required reoperation between the index surgery and the 30-day follow-up assessment.

The results of the RAVEN Study demonstrate the Dexter L6 System is safe and effective for subjects undergoing ventral hernia repair.

Conclusions:

The subject Dexter L6 System and the predicate Dexter L6 System (K251197) have the same intended use, similar indications for use and same technological characteristics. The expanded indications for use do not change the intended use of the device and do not raise new or different questions of safety and effectiveness. Analysis and clinical performance data of the device demonstrate that the Dexter L6 System is as safe and effective as the predicate device, when used as labeled. Thus, the subject Dexter L6 System is substantially equivalent to the predicate device.