June 11, 2026

Distalmotion SA
Caroline Bonnet
Regulatory Affairs Specialist
Contact Address

Re: K260653
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: [NOTE: Use date of most recent supplement]
Received: February 27, 2026

Dear Caroline Bonnet:

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: 2026.06.11 15:59:16 -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.	K260653

Please provide the device trade name(s).

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 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)

510(K) SUMMARY

DISTALMOTION DEXTER L6 SYSTEM

Submitter: Distalmotion SA
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1066 Epalinges
Switzerland

Contact: Caroline Bonnet
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Date Prepared: June 9, 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 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, 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.

The Dexter L6 System is for prescription use only.

Summary of Technological Characteristics:

The subject device has the same technological characteristics as the predicate device, the Dexter L6 System (K251197). The labeling has been changed to address use of the device in sacrocolpopexy 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 sacrocolpopexy 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 SPARO (*Robotic Sacrocolpopexy and Sacrocervicopexy - an observational study to confirm the peri- and postoperative safety and clinical performance*) 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 sacrocolpopexy or sacrocervicopexy.

The SPARO Study included 35 subjects on whom robotic-assisted surgery with Dexter was at least started (mITT population). Amongst the 35 subjects, the mean age was 65 ± 11.4 years. The mean BMI was 27.1 ± 4.4 kg/m2. The mean value for the POP-Q Point C measurement was -1.3 ± 2.1 cm. POP-Q stage III was the most prevalent: 40.0% (14/35), followed by stage II: 34.3% (12/35). The

patient population was primarily White (88.6%) followed by Asian (5.7%), with the remaining 5.7% being of other or mixed racial backgrounds.

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 34 out of 35 procedures (97.1%). No conversions to open surgery were recorded in the study.

For the primary safety endpoint, there were three (8.6%) Clavien-Dindo grades III-V events perioperatively up to 42 days in three subjects with: hematoma (Grade IIIb requiring reoperation), lower compartment leg syndrome (Grade IIIb requiring reoperation) and genitourinary tract infection (Grade IIIa requiring re-hospitalization). All three events were resolved at the time of the 42-day follow-up visit.

In conclusion, the results of the SPARO Study demonstrate the Dexter L6 System is safe and effective for subjects undergoing sacrocolpopexy or sacrocervicopexy.

Conclusions:

The subject Dexter L6 System has the same intended use 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 demonstrate that the Dexter L6 System is as safe and effective as the predicate device. Thus, the subject Dexter L6 System is substantially equivalent.