DE NOVO CLASSIFICATION REQUEST FOR

DEXTER L6 SURGICAL SYSTEM

Regulatory Information

FDA identifies this generic type of device as:

> **Electromechanical surgical system with transient sterile field presence of both surgeon and primary control interface.** An electromechanical surgical system with transient sterile field presence of both surgeon and primary control interface is a software-controlled electromechanical system with fully positionable patient/device interfaces which allows a qualified user to perform surgical techniques during minimally invasive surgical procedures. The device allows for both the surgeon and primary control interface to have presence inside the sterile field as needed within the clinical context of use.
>
> **NEW REGULATION NUMBER:** 21 CFR 878.4965
>
> **CLASSIFICATION:** Class II
>
> **PRODUCT CODE:** SDD

BACKGROUND

DEVICE NAME: Dexter L6 Surgical System

SUBMISSION NUMBER: DEN230084

DATE DE NOVO RECEIVED: December 15, 2023

SPONSOR INFORMATION:

Distalmotion, SA
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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, dissecting, coagulating and cutting, with or without high frequency functionality. The Distalmotion Dexter L6 System is intended for use in laparoscopic inguinal hernia repair. The system is indicated for adult uses, as defined as 22 years old

and older. It is intended for use by trained laparoscopic 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.

LIMITATIONS

The sale, distribution, and use of the Dexter L6 Surgical System are restricted to prescription use in accordance with 21 CFR 878.4964.

The device is only for distribution to facilities that implement and maintain the device specific use training program and ensure that users of the device have completed the device specific use training program. Only trained users and those who have developed adequate robotic skills to perform the tasks associated with each procedure should use the Dexter L6 System. Training provided by Distalmotion is limited to the use of the Dexter L6 System and does not replace the necessary medical training and experience required to perform laparoscopic surgery.

The demonstration of safety and effectiveness for the representative-specific procedures was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of the patient's underlying disease or condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Dexter L6 Surgical System is intended to assist in the accurate control of its surgical endoscopic instruments across a range of surgical procedures. The system is comprised of two major elements, the Surgeon Console and the Patient Cart. The surgeon console allows the surgeon to scrub into the surgical field, and either in seated or standing position, allows control of the instrument and endoscope arms on the patient cart. The Surgeon Console provides the surgeon two handle grips and two pedals, one pedal to clutch instrument control and a second to engage endoscope control. The patient cart is a modular element of the system which is comprised of a pedestal and boom which support the instrument arm. The instrument arm on the patient cart is controlled by the Master Arms on the surgeon cart. The Master Arms are passive elements on the surgeon cart which translate the movements of the surgeon to the Instrument arms. A system overview is provided in Figure 1, including surgeon console, patient carts, and endoscope cart. Figure 2 shows end effectors cleared for use on the system. In addition to the major elements of the system certain reusable and disposable sterile accessories are cleared with the Dexter L6 system, shown in figures 3 and 4.

Surgeon Console	Patient Cart 1	Patient Cart 2	Endoscope Cart
			

Figure 1: System Overview

Needle Holder	Bipolar Johann Grasper	Bipolar Maryland Dissector	Monopolar Scissors	Monopolar Hook
				
	Rated voltage of 770 Vp	Rated voltage of 770 Vp	Rated voltage of 4000 Vp	Rated voltage of 4000 Vp

Figure 2: Instrument End Effectors and Peak Voltage rating

Accessory Tray	Handle Grip	Incision Pointer	Emergency Release Tool
			
1x	2x	2x	1x
To transport, store and reprocess the Handle Grips, the Incision Pointers and the Emergency Release Tool.	Connected to the Surgeon Console. Held by the surgeon to control the Dexter L6 System.	To dock the Patient Carts to the trocars.	To open instrument blades when the Dexter L6 System stops working and instruments grab tissue.

Figure 3: Reusable Accessories

Sterile Drapes	Sterile Interfaces
	
• 3x Sterile Drapes for the Surgeon Console: Left Master Arm, right Master Arm and central pillar. • 2x Sterile Drapes for the Patient Cart: Left Patient Cart and right Patient Cart.	• 2x Inserted into the Hub.

Figure 4: Disposable Accessories

The Dexter L6 System and accessories:

- Dexter L6 (DM-L6):
  - Surgeon Console (SC), which is the primary user interface for the surgeon for controlling the instrument arms. The surgeon console comprises:
  - Master Arms (SC-MA), which capture physician's arm movements.

    - Handles (SC-H), which connect to the Handle Grips and capture surgeon's hand movement.
    - Wheelbase (SC-WB), which allows transport, OR positioning and console securing.
- Patient Carts (PC), which is placed bedside for holding the laparoscopic surgical instrument. Two patient carts are provided with the system, where each comprises:
    - Hub (PC-H), which interfaces with the instrument and contains the actuators that drives the instrument movements (micro-movements).
    - Instrument Arm (PC-IA), which supports the hub and replicates surgeon's arms movements (macro-movements).
    - Boom (PC-B), which holds the instrument arms and allow its horizontal positioning.
    - Wheelbase (PC-WB), which allows transport, bedside positioning and cart securing.
- Software which contains safety architecture and motion control algorithms.
- Instruments, available in the following 5 models:
    - Monopolar Scissors (IN-MS), which allows performing cutting and cauterization steps.
    - Monopolar Hook (IN-MH), which allows performing cutting and cauterization steps.
    - Bipolar Maryland Grasper (IN-BM), which allows performing grasping and cauterization steps.
    - Bipolar Johann Grasper (IN-JG), which allows performing atraumatic grasping and cauterization steps.
    - Needle Holder (IN-NH), which allows performing suturing steps.
- Endoscope Arm (SOLO, third party), which holds and controls the movement of another third-party endoscope. It comes with accessories – which are used to secure the third-party endoscope to the Endoscope Arm – and drapes.
- Endoscope Cart (EC), which supports the Endoscope Arm.
- Accessories
    - Sterile Interface (AC-SU-SI), which provides a sterile and electrical barrier between the instrument and the hub.
    - Handle Grips (AC-RU-HG), which connect to the surgeon console handles and capture surgeon's hand movement.
    - Incision Pointers (AC-RU-IP), which are used to dock the instrument arms.
    - Emergency Release Tool (ERT), which are used to release the instrument in case the system cannot be operated.
    - The Accessory Tray (AC-RU-T), which serves as a container for all accessories to be reprocessed.
    - Sterile Drape (AC-SU-SD), which serves as a sterile barrier for the surgeon console, the patient carts

SUMMARY OF NONCLINICAL/BENCH STUDIES

The following non-clinical test were leveraged to demonstrate safety and effectiveness for the subject device's indication for use.

The Dexter L6 Surgical System has components that are in direct patient contact. The patient contacting portion and materials were assessed in accordance with ISO 10993-1:2018 and FDA Guidance *"Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* Table 1 summarized biocompatibility testing completed for the Dexter L6.

TABLE 1. BIOCOMPATIBILITY/MATERIALS

Test	Method	Results
Cytotoxicity	MEM Elution - ISO 10993-5	PASS
Sensitization	ISO 10993-10 – Sensitization Assays	PASS
Irritation	ISO 10993-21 - Intracutaneous Injections Test	PASS
Acute Systemic Toxicity	ISO 10993-11 - Systemic Injection Test	PASS
Material-mediated Pyrogenicity	ISO 10993-11 – Rabbit Pyrogen Test	PASS

Cleaning, disinfection, and sterilization validation testing was undertaken for all relevant elements of the Dexter L6 Surgical System (Table 2).

Device Integrity/Use-life Testing:

Each article was processed through a total of 30 cycles. Each cycle consisted of a automated cleaning procedure followed by a sterilization cycle. Following the completion of the cleaning of each cycle, the articles were visually inspected for any sign of physical damage or corrosion, including cracking, flaking, pitting, and formation of rust. The reprocessing cycles were performed with the worst sterilization parameters along with simulated use (mechanical fatigue/wear testing). For the hand grips evaluation of test sample by minitab 19 for 2 samples for an equivalence of 30 uses with no failure and a Weibull shape factor of 3 is the following: 291,399 movements for 60000 actuations and 2916 movements for 600 releases. Knowing that 1 cycle is 2 movements (opening + closing).

TABLE 2. SHELF LIFE/STERILITY

Test	Method	Results
Dexter L6, Customer Card		
Sterilization	ISO 11135:2014	PASS
Dexter L6, Sterilization Validation Protocol		
Sterilization	ISO 11135:2014, ANSI / AAMI / ISO 11737-1, ANSI / AAMI / EN ISO 11737-2, ISO 11138, EN 556-1, ISO 10993-7, EN ISO 13485, EN ISO 11607, EN 1422	PASS
Dexter L6, Surgical Instruments		
Sterilization	SN ISO 11737-1 - European Pharmacopoeia ch. 2.6.12 and USP (61)	PASS
Dexter L6, Reusable Accessories (Handle Grips, Incision Pointer, and Tools)		
Cleaning	ANSI/AAMI ST98:2022; ISO 10993-5:2009, AAMI TIR12:2020, AAMI TIR34:2014/(R)2021, ISO 17664-1:2021, ASTM F3208-20, AAMI ST 15883-1:2009/(R)2023	PASS
Disinfection	ANSI/AAMI ST98:2022; ISO 10993-5:2009, AAMI TIR12:2020, AAMI TIR34:2014/(R)2021, ISO 17664-	PASS

	1:2021, ASTM F3208-20, AAMI ST 15883-1:2009/(R)2023	
Sterilization	ANSI/AAMI/ISO 17665-1:2006/(R)2013; ANSI/AAMI/ISO 11138-1:2017, ANSI/AAMI/ISO 11138-3:2017, ISO 17664-1:2021, ISO 11138-7:2019, ISO 11737-2:2019, ANSI/AAMI ST79:2017 and 2020, EN285:2015 + A1:2021	PASS

The system was evaluated to ensure basic functionality after shipping and distribution (Table 3).

TABLE 3. ENVIRONMENTAL AND DISTRIBUTION TESTING

Test	Method	Results
Environmental & Distribution Testing	ISTA 3A-18, ASTM D4332-22, ASTM D5276-19, ASTM D4728-17 (2022), ASTM D6653/D6653M-13 (2021), D4728-17 (2022)	PASS

The EMC and Electrical Safety was evaluated to mitigate the risk of electrical fault resulting in injury to patient or user. Table 4 identifies the Electrical/ Mechanical/Thermal Safety, and electromagnetic compatibility (EMC) testing that has been performed. Production batch instruments were sterilized prior to 60601-1 and collateral (including -2-2) testing.

TABLE 4. ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

Test	Method	Results
Electrical Safety, & Usability	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 for use in conjunction with IEC 62366-1:2015, AMD1:2020, and IEC 60601-1:2005, AMD1:2012, AMD2:2020, (Usability/Human Factors) IEC 60601-2-18:2009 for use in conjunction with IEC 60601-1:2005, (endoscopic equipment) IEC 80601-2-77:2019 for use IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012, (RASE) IEC 60601-2-2:2017 for use in conjunction with IEC 60601-1:2005, (HF surgical equipment)	PASS
EMC (Immunity)	IEC 60601-1-2:2020(Electromagnetic disturbances)	PASS
EMC (Emissions)	IEC 60601-1-2:2015	PASS

MAGNETIC RESONANCE (MR) COMPATIBILITY

This device is not MR compatible and should not be used in or near MR equipment.

SOFTWARE

A failure or latent flaw in the software of the Dexter L6 Surgical System could directly result in severe injury or death to the patient; therefore, the software of this device is considered to require "Enhanced Documentation".

The submission contained all the elements of "Enhanced Documentation" corresponding to a "Major" level of concern, as outlined in the FDA guidance document " Content of Premarket Submissions for Device Software Functions ", issued June 14, 2023 (https://www.fda.gov/media/73065/download). Adequate documentation describing the software, firmware, software specifications, architecture design, software development environment, traceability, revision level history, unresolved anomalies and cybersecurity provide the foundation that the software will operate in a manner as described in the specifications. A hazard analysis was performed to characterize software risks including device malfunction and measurement related errors. The submission included verification and validation (V&V) testing to address the potential hazards with satisfactory results.

PERFORMANCE TESTING - BENCH

The following bench tests were performed to mitigate the risks of thermal, electrical, and mechanical fault which may result in injury to patient or user, tissue damage and/or injury due to system malfunction, user error which may result in patient injury. Bench testing also addressed unique risks associated with the design of the Dexter L6 surgical system.

The bench tests characterize device performance and design verification for the Dexter L6 Surgical System. All applicable testing was performed with provided and third-party devices. The descriptions and results of the bench tests are summarized in Table 5.

TABLE 5. BENCH TESTING

Test Description	Objective	Results
System Testing	The intent of this section is to demonstrate that the device satisfies the requirements ensuring the motion replication performance, Endoscope Control essential performance, Safe State Transition and Emergency Stop essential performances, Protective Stop defined as "Once the RASS enters the PROTECTIVE STOP, the instruments motion replication is stopped, the brakes are not engaged, and the RASS continues to monitor the error triggering condition, Release of the Patient, Visual feedback is provided by the LED ring on the HUB	PASS
Accuracy and Precision	The activities in this section aim to verify that the Dexter L6 System meets the product requirement specifications related to motion control performance. Specifically Accuracy and	PASS

	Precision of the position control of the instrument, as well as the Minimum Controllable Motion, Minimum Measurable Motion, and latency of the motion. Furthermore, the integration with the 3rd Party endoscope arm is verified by measuring the speed Accuracy. The testing shall provide evidence of the Dexter L6 System's ability replicate the surgeon's movements into corresponding motion, controlling instrument's pose (position + orientation). This shall be assessed systematically by verifying the performance of each related subsystem (master arm, instrument arm, endoscope arm) in terms of accuracy and precision, as well as the performance of the Dexter L6 System as a whole.	
Workspace access	All non-clinical tests executed to evaluate the capability of the robotic arm to move the instrument tip at any location of the workspace maintaining the RCM, independently of the surgical procedure. The RCM is defined as the Remote Center of Motion is a fixed point in space that is always aligned with the instrument shaft. The RCM is a feature which ensures that the surgical instruments rotate around their incision ports (trocar), thereby minimizing the risk of harm to surrounding tissues.	PASS
System set-up	Verify the compatibility and combinations performance and safety of the mounting hardware with the robot by testing interfaces or reviewing design specifications.	PASS
Performance testing with compatible devices	Additional testing that is not fully covered by the above mentioned assessment: compatibility with Surgical Table and electrical connectors of the Instruments to the commercially available Electrosurgical Generator cords.	PASS
Sub-system testing, encompassing for the Surgeon Console: Mechanical Balance and Motion Smoothness, Functional Tests, Mechanical Rigidity and Resistance, Mechanical Balance and Motion	Non-clinical bench testing is needed on the Surgeon Console subsystem to focus on mechanical aspects and data acquisition process performance, as well as mechanical and electrical reliability	PASS

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	Non-clinical bench testing is needed on the Patient Cart subsystem to focus on actuation and mechanical aspects, performance of replicating the input motion data, as well as mechanical and electrical reliability	PASS
Instruments, encompassing for all the instrument types: Functional Tests, Mechanical Rigidity and Resistance, Mechanical and Electrical Reliability, Micro Workspace	Functional Tests section comprises all testing completed to ensure stable and constant functionality of the Dexter's Instruments. The Mechanical rigidity and resistance section challenges the strength of the Instruments while the Mechanical and electrical reliability challenges the endurance and safety. Finally, the Micro workspace section gives an overview of the mechanical tip workspace limitation. The capture of the movements, the closing forces, the replication and the accuracy of the Dexter system including the Instruments are discussed in previous sections 4.3 - Tests Executed and 5 - Workspace access, as part of system testing and device motion accuracy testing respectively.	PASS
Accessories, encompassing specific tests for Sterile Interface, Endoscope Cart, and the Sterile Drapes. To be noted that reusable accessories are assessed in specific reprocessing and durability reports, in the Shelf Life and Packaging Validation sections.	Tests to demonstrate functionality, safety and reliability of the following accessories. The accessories are used in the context of the surgical procedure in order to make up for specific system requirements. The Dexter L6 system accessories are: * Sterile interface (AC-SU-SI) * Endoscope cart (DM-L6-EC) * Sterile drapes (AC-SU-SD) Reusable accessories are assessed in specific reprocessing and durability reports, in the Shelf Life and Packaging Validation sections. This concerns: * Accessory Tray * Handle Grip * Incision pointer * Emergency release tool	PASS
Thermal effects on tissue	Evaluate the thermal effects on tissue caused by the electrosurgical functionalities of the Dexter L6 Electrosurgical Instruments	PASS

TRAINING

The sponsor has developed a Dexter L6-specific use training program to ensure proper device setup/use/shutdown, accurate control of instruments to perform the intended surgical procedures, troubleshooting and handling during unexpected events or emergencies, and safe practices to mitigate use error. Dexter L6 Surgical Systems are distributed only to facilities that implement and maintain the device-specific use training program, including assurance that users of the device have completed the device-specific use training program.

HUMAN FACTORS TESTING

The Human Factors activities focused on developing the Dexter L6 Surgical System to facilitate safe and effective use by the intended users in the intended use environment. All activities were carried out in accordance with FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices", February 2016. The system was assessed through Human Factors activities in markets outside of the US, formative studies, and US Human Factors validation study.

The US validation study evaluated the training of surgical teams to complete a selection of evaluation activities (i.e., use scenarios [US] and knowledge tasks [KT]) to validate mitigations the Sponsor implemented to reduce the risk associated with critical tasks.
Evaluation activities during the test session, each participant performed various tasks within representative, naturalistic use scenarios. Participants also performed knowledge tasks to evaluate critical tasks that cannot be evaluated during the hands-on use scenarios.

SUMMARY OF CLINICAL INFORMATION

To support the De Novo request and gather evidence addressing the safety and efficacy profile of the Dexter system for use in the repair of inguinal hernias, Distalmotion conducted the the **R**obotic minim**A**lly inva**S**ive inguin**A**l **H**ernia r**E**p**A**ir with **D**exter, RAS AHEAD Study. The purpose of this clinical investigation is to confirm the perioperative and early postoperative safety and clinical performance of the Dexter Robotic System, in subjects undergoing primary transperitoneal unilateral or bilateral inguinal hernia repair. The clinical investigation was conducted in accordance with Good Clinical Practice (GCP) as described in 21 CFR 812.28(A)(1).

Study Design, Including Study Population and Investigation Period:

Single-arm, prospective, multicenter, open-label, clinical investigation. A total of 50 adult subjects across a minimum of three centers, were planned to be treated with the study device to demonstrate that the device fulfils its intended function adequately and that it was safe in doing so. The total was to ensure that at least 45 subjects completed the study for analysis.

A subject was considered "as treated" when at least one procedural step was started with the study device.

Subjects enrolled before surgery and followed up intra-operatively as well as post-operatively up to 30 days (+7 days) after the procedure. The study duration from the first procedure to the last follow-up assessment was 5 months.

Demographics:

Table 70 below provides a summary of the study population's demographics:

Table 70: Demographics

	mITT(N=50) Proportions presented as: % (n/N). (95% Exact CI)
Age (years)	
Mean ± SD	60.1 ± 15.2
(95% CI of Mean)	(55.8, 64.4)
Median	62.5
Min, Max	27.0, 89.0
Race*	
Asian	0.0% (0/50), (0.0%, 7.1%)
Black or African-American	2.0% (1/50), (0.1%, 10.6%)
White/Caucasian	58.0% (29/50), (43.2%, 71.8%)
Unknown or not reported	40.0% (20/50), (26.4%, 54.8%)
Gender	
Male	94.0% (47/50), (83.5%, 98.7%)
Female	6.0% (3/50), (1.3%, 16.5%)
BMI (kg/m^2)	
Mean ± SD	25.7 ± 3.3
Median	(24.8, 26.6)
Min, Max	25.1
	18.4. 34.0
ASA Status	
ASA I – a normal healthy subject	26.0% (13/50), (14.6%, 40.3)
ASA II – a subject with mild systemic disease	66.0% (33/50), (51.2%, 78.8%)
	8.0% (4/50), (2.2%, 19.2%)
ASA III – a subject with severe systemic disease	

**Collecting information on race is considered sensitive data in certain European countries and was therefore not documented for the subjects enrolled in France (20 subjects).*

Study Endpoints:

Primary endpoint:

- **Safety:** Occurrence of adjudicated serious (Clavien - Dindo grades III-V), device related, adverse events perioperatively up to 30 days.

- **Performance:** Procedural success, defined as successful completion of the Dexter-assisted procedure, i.e. free of any conversion to an open or fully laparoscopic surgical approach.

Secondary endpoints:

- **Secondary safety endpoints:**
  1. Intraoperative Adverse Events and Complications
  2. Postoperative complications up to 30 days post-operative (according to Clavien Dindo)
  3. Device-related Adverse Events
  4. Procedure related Adverse Events
  5. Blood loss, measured in ml
  6. Mortality
  7. Re-hospitalization

- **Secondary performance endpoints**
  1. Duration of docking time, measured in minutes
  2. Operative time, measured in minutes (cut to suture)
  3. Total time of robot in use
  4. Instrument consumption measured in number of robotic instruments used
  5. Use of extra trocar sites
  6. Unplanned surgical steps

- **Other endpoints of interest**
  1. Postoperative hospital stay, measured in days from first day after operation to discharge
  2. Reoperation
  3. Pain score through VAS

Enrollment Criteria:

Inclusion criteria:
- Aged > 18 years
- Subjects planned to undergo elective robot-assisted and laparoscopic surgery for primary unilateral or bilateral inguinal hernia repair using one camera port, two ports for the manipulating instruments, and additional ports as needed.
- Subject agrees to perform the 30-day follow-up assessment
- Able to provide signed Informed Consent, according to local regulation

Exclusion criteria:

General

- As per Instructions for Use:
  - Morbidly obese patients (BMI > 40)
  - Any relative and absolute contraindications for the use of conventional endoscopes and endoscopic surgical instruments
  - Need for robotic stapling, advanced energy delivery, ultrasound, cryoablation and microwave energy delivery
  - Bleeding diathesis
  - Pregnancy
  - Subjects with pacemakers or internal defibrillators
- Any planned concomitant procedures

- Subject deprived of liberty by administrative or judicial decision or under legal guardianship.
- Participation in another interventional clinical trial

Procedure-specific
- Emergent inguinal hernia repair
- History of major* abdominal or pelvic surgery
- Strangulated and incarcerated inguinal hernia
- Large scrotal hernia **
- Prior prostatectomy, hysterectomy and any other uterine procedures
- Prior radiotherapy for prostatic cancer
- Previous preperitoneal mesh placement on the side of the planned inguinal hernia repair.

** Major is being defined as any previous surgery that involved a large abdominal incision (> 10 cm) and/or an extensive resection of organs that significantly altered the normal anatomy.*
*** Large scrotal hernia = when the hernia sac reaches the scrotum*

Study Investigators:

A total of three Investigators participated in this clinical study and performed the inguinal hernia procedures:
- Surgeon #1 (Centre Hospitalier de Saintes – France): 20 subjects
- Surgeon #2 (Kantonspital Winterthur – Switzerland): 20 subjects
- Surgeon #3 (UKSH Kiel – Germany): 10 subjects

All surgeons went through a dedicated training curriculum ensuring that all successfully trained participants are capable of safe and effective usage of the Dexter System according to their roles in the OR.

All three investigators are general surgeons, their ***experience in robotic surgery ranged from 9 months to 5 years.*** Additional information on the surgeons' laparoscopic and robotic experience is provide below:

Table 68: Surgeon's experience

Surgeons	Laparoscopic (LAP) Experience		Robotic Assisted Surgery (RAS) Experience		Dexter System Experience	
	Years of LAP experience	Estimated number of LAP procedures completed before study start	Years of RAS experience	Estimated number of RAS procedures completed before study start	Number of Dexter procedures completed before study start	Number of inguinal hernia procedures completed with Dexter before study start
Surgeon #1	35	several thousands	17 months	46	46	41
Surgeon #2	7	500	9 months	67	42	28
Surgeon #3	19	> 2600	5	290	38	7

Table 68: Surgeon's experience

Surgeons	Laparoscopic (LAP) Experience		Robotic Assisted Surgery (RAS) Experience		Dexter System Experience	
	Years of LAP experience	Estimated number of LAP procedures completed before study start	Years of RAS experience	Estimated number of RAS procedures completed before study start	Number of Dexter procedures completed before study start	Number of inguinal hernia procedures completed with Dexter before study start
Surgeon #1	35	several thousands	17 months	46	46	41
Surgeon #2	7	500	9 months	67	42	28
Surgeon #3	19	> 2600	5	290	38	7

Clinical Study Results:

Effectiveness Results:
Primary performance: Defined as successful completion of the Dexter-assisted procedure without conversion to an open or fully laparoscopic surgical approach, was confirmed in 49 of 50 procedures (98.0%).

In one subject, the procedure was converted to the laparoscopic mode because of work space limitation due to a non-optimal placement of the trocars. The trocars were placed too low (caudal) such that the surgeon was unable to reach the entire surgical area with the device. The surgeon safely completed the surgery in the laparoscopic mode, with no adverse event reported for this subject.

Secondary performance:
- Duration of docking time, measured in minutes [Time Frame: Intra-operative]: The mean duration of docking time was 4.2 min (SD 2.0; range: 1.0 to 11.0 min).
- Operative time, measured in minutes (skin to skin) [Time Frame: Intra-operative]: The mean operative time was 54.5 min (SD 14.2; range: 28.0 to 93.0) for unilateral and 94.6 min (SD 22.2; range: 47.0 to 143.0 min) for bilateral inguinal hernia repair.
- Total time of robot in use: The mean total time of robotic use was 34.4 min (SD 11.6; range: 16.0 to 58.0 min) for unilateral and 68.3 min (SD 20.7; range: 22.0 to 108.0) for bilateral inguinal hernia repair.
- Instrument consumption, measured in number of robotic instruments used [Time Frame: Intra-operative]: Procedures were performed with three instruments (96.0%) or four instruments (4.0%).
- Use of extra trocar sites: None of the procedures required the placement of extra trocars.
- Unplanned surgical steps: An unscheduled surgical step was required during three right-sided inguinal hernia procedures. All three unscheduled surgical steps referred to adhesiolysis and were performed with the robotic system.

Safety Results:

Primary safety endpoint:
There were no postoperative serious (Clavien-Dindo grades III-V), device related, adverse events perioperatively up to 30 days. Adverse Events were reviewed by a CEC, none of the events were assessed as endpoint related.

Secondary safety endpoints:

- Intraoperative Adverse Events and Complications [Time Frame: Intra-operative (grading according to ClassIntra)]: There were no intraoperative adverse events and complications.

- Postoperative complications up to 30 days post-operative (according to Clavien-Dindo): There were 12 (18.0%) postoperative complications up to 30 days follow-up, thereof 11 (16.0%) Clavien-Dindo grade 1 complications and one (2.0%) Clavien-Dindo grade 2 complication (2.0%).

    - No intra-operative Adverse Event was reported. Hematoma and seroma were the most frequently reported Adverse Events, both with 6% of occurrence.
    - 11 (16%) events were classified as Clavien-Dindo I, only 1 (2%) event (small intestine occlusion) was classified as Clavien-Dindo II.
    - None of the reported Adverse Events were considered as device-related.
    - Hematoma (3x):
    - - None of the reported hematoma required treatment/intervention' 2 out of the 3 hematomas were resolved at study completion.
    - Seroma (3x)
    - - None of the reported seroma required treatment/intervention, all events were ongoing at study completion.
    - Persistent groin pain (1x)
    - - Subject received pain killer medication, event was ongoing at study completion with a VAS of 10mm, which can be considered as mild pain.
    - Trocar specific complication – hyperesthesia (1x)
    - - No treatment/intervention was required, event was ongoing at study completion.
    - Anesthesia complication – nausea (1x)
    - - No treatment/intervention was required, event was resolved at study completion.
    - Other Adverse Events (3x)
    - - 1x small intestine occlusion: subject was re-hospitalized and received medications, event was resolved at study completion.
    - - 1x erectile dysfunction secondary to hematoma: no treatment/intervention, event was resolved at study completion.
- - 1x mild traumatic brain injury caused by a fall on the head: not procedure related, no treatment/intervention, event was resolved with sequelae at study completion.Device-related Adverse Events [Time Frame: Intra-operative – within 30 post-operative day]: No device-related adverse events were reported.
- Procedure-related Adverse Events [Time Frame: intra-operative – within 30 post-operative day]: There were 11 (16%) procedure-related adverse events up to 30 days follow-up, thereof 10 (16.0%)
- Mortality [Time Frame: intra-operative - within 30 post-operative day]: There was no patient death.
- Blood loss, measured in ml [Time Frame: Intra-operative]: The mean intraoperative blood loss was 5.5 mL (SD 7.3; range 0.0, 20.0 mL). No intraoperative blood transfusion was needed.
- Re-hospitalization [Time Frame: discharge – within 30 postoperative day]: One subject (2.0%) was re-hospitalized after being discharged after the index procedure
- Subject discontinuations: The study cohort included 51 enrolled subjects. The mITT population, defined as subjects who were enrolled and on whom robotic-assisted surgery

with Dexter was at least started, included 50 subjects. One subject (2.0%) was withdrawn from the study for meeting an exclusion criterion (large scrotal hernia).
- Subject complaints: no subject complaints were reported.
- Device failures: no device failures were reported.

Comparator Group:

Clinical performance and safety was compared to literature reporting for "primary unilateral or bilateral inguinal hernia via minimally invasive surgery", prepared by and independent contractor, (b)(4); (b)(6) The report discusses relevant clinical data on the safety and performance of robotic inguinal hernia repair (rIHR). For this, searches in the scientific literature were performed, including specific searches on the use of the comparative devices Da Vinci (manufacturer Intuitive Surgical, California, U.S.) and Senhance (manufacturer Asensus Surgical, North Carolina, U.S.).

The majority of studies evaluated the use of the da Vinci systems in the conduction of rTAPP (robotic transabdominal peritoneal) repair.

Systematic searches were conducted in PubMed. PubMed covers the international literature of every field of medicine and comprises more than 26 million citations for biomedical literature.

The primary component is the bibliographic database MEDLINE (Medical Literature Analysis and Retrieval System Online) which on its features approx. 5,600 international scholarly journals of the biomedicine and health sector. Furthermore, PubMed covers a wide range of life science journals, online books as well as citations that precede the date that the respective journal was selected for MEDLINE indexing.

The database search strategy was based on the definition of string searches that appropriately reflect the objectives of the present ER. Additional details are provided in the following table.

Table 74: Search terms and strings defined for the systematic literature searches

Source	Search terms	Filters	Findings	Included
MEDLINE PubMed	(Robot OR Robotic) AND ("unilateral inguinal hernia repair")	Last 10 years	3	3
	(Robot OR Robotic) AND ("bilateral inguinal hernia repair")	Last 10 years	3	2
	(Robot OR Robotic) AND ("inguinal hernia repair") AND ("safety" OR "performance")	Last 10 years	32	22
	("Senhance" OR "da Vinci") AND "inguinal hernia repair"	Last 10 years	15	5
Total			**53**	**32**

The following criteria were used to select potentially relevant publications.

Table 75: Inclusion and exclusion criteria

Inclusion Criteria	The publication addresses the State-of-the-Art technology and provides relevant clinical information pertaining to the safety and performance of robotic devices used for inguinal hernia repair
	The study design is appropriate to answer the proposed questions of the study (applicable when the publication is derived from clinical studies)
	The publication presents sufficient information for a rational and objective assessment
Exclusion Criteria	Full-text and/or publication not available
	The publication is a duplicate. Each publication will be considered only once. In the case of updated versions of meta-analyses or systematic reviews, the most recent/updated version will be chosen
	Language is not English or English translation
	The publication is derived from a pre-clinical study (e.g., in-vitro, animal models, bench testing) or phantom study
	The publication focus on the description of surgical technique, study protocol, and/or other similar data that do not provide relevant clinical information on the safety, performance, usability, and/or off- label use of the device

Moreover, five additional publications were provided by the manufacturer Distalmotion, although one was excluded according to the above-mentioned criteria.

For further details about the search results, including the included and excluded articles, please see the Literature Search Report documented in the Expert Report [**Attachment 007330 - Expert Report Literature Review (Distalmotion_ER_SP_IHR_rev01)**].

This summary outlines the key elements of the Expert Report and relates them to the completed prospective inguinal hernia study with the Dexter System (RAS Ahead study #2023-01). The report is provided in **Attachment 007330 - Expert Report Literature Review (Distalmotion_ER_SP_IHR_rev01)**.

Medical History (Comorbidities)

Clinical data from comparative devices were extracted from a total of 19 publications.

Demographics

Literature Report:

The comparator population was composed mainly of men, mostly aged between 40 and 60 years. As suggested by the average BMI values, most of the subjects were either overweight or obese and although the presence of comorbidities was not reported by all the publications, individuals seem to be affected primarily by cardiovascular and metabolic complications, with hypertension (prevalence range: 29 - 46%) and diabetes (prevalence range: 7 - 15.8%) being the most frequently reported conditions. Nevertheless, some studies also reported a considerable number of patients with coronary artery disease (CAD, range: 5.1 - 16%) and chronic obstructive pulmonary (COPD, range: 5.1 - 11%).

A relevant number of individuals had a history of previous surgery, as between 21 and 48% of the patients had already undergone abdominal surgery. Regarding the American Society of Anesthesiologists (ASA) score, the majority of subjects were classified as Score 2 (moderate) and Score 3 (moderate to severe), and unilateral hernias were more frequently observed than bilateral cases. Cases of recurrent hernias were reported in different ranges, varying from 6.3 to 28.2%, and incarcerated hernias were not frequently found (1.9 - 5.1%).

RAS Ahead Study with Dexter:

The treated population of the inguinal hernia study with Dexter is composed mainly of men (94%). The mean age of the studied population is 60.1 years. With a mean BMI of 25.7, slightly more than half of the population falls within the overweight range. The most frequently reported comorbidities are hypertension (22%), coronary artery disease (10%) and type II diabetes (8%).

The majority of the subjects presented an ASA score of II (66%); for 8% of the study population de ASA score was III. More patients presented an unilateral hernia than a bilateral hernia (66% vs. 34%). Patients with a history of major abdominal or pelvic surgery were excluded from the study.

Comparison of Study group to Literature Comparator group:

Both the study and comparator cohorts consisted mostly of male subjects with unilateral hernias. The comparator cohort appears to be comprised of patients with slightly lower BMI compared to the study population. However, the rates and types of co-morbid conditions appear to be similar, with a similar distribution of ASA scores between both cohorts. Another difference between the comparator cohort and study population is the inclusion of both recurrent and incarcerated hernia (which were specifically excluded in the study population). However, considering the similarities and differences between the study and comparator cohorts, it appears the literature cohort represents a valid comparator group which may assist in the benefit risk assessment of the subject device.

Table 76: Most frequent comorbidities

Most Frequent Comorbidities	**RAS Ahead (Dexter) (n=50)**	**RWE (Expert Report)**
Hypertension	**11 (22%)**	prevalence range of 29 - 46%
Coronary artery disease	**5 (10%)**	prevalence range of 5.1 - 16%
Type II diabetes	**4 (8%)**	prevalence range of 7 - 15.8%)

Conclusion

The prospective study on the treatment of inguinal hernia enrolled a patient population with comorbidities that are representative of the RWE population as described in the Expert Report.

Both, the Expert Report and the RAS Ahead study do report a study population primarily affected by cardiovascular and metabolic complications including hypertension, coronary artery disease and diabetes. The reported values from the RAS Ahead study are in line with the values reported from the RWE, except the hypertension rate which is lower for the RAS Ahead study. A recent study published by Hajili et al. in 2023 concluded that the TAPP method for patients with cardiovascular disease does not elevate the individual perioperative risk *(Kamran Hajili, Alberto Vega Hernandez, Jakob Otten, Dana Richards, and Claudia Rudroff, "Risk factors for early and late morbidity in patients with cardiovascular disease undergoing inguinal hernia repair with tailored approach: single-center cohort study.," BMC Surgery, 2023)*.

Conversion Rates and Operative Time:

Literature Report:

Conversion rates to open surgery and total operative time are frequently used as parameters to assess the performance of the device. Conversion rates were reported by 16 out of 19 studies. Six publications reported no cases of conversion to open surgery and two publications informed no cases of conversion either to open or to laparoscopy [12] [26]. Aiolfi et al found a pooled prevalence of conversion of 0.14%, and the other publications also reported very low conversion rates, mainly below 2%. In particular, Maas and colleagues evaluated conversion rates to laparoscopy, and not to open surgery. Two cases of conversion to laparoscopy occurred among 43 patients (4.6%).

All the selected studies reported the operative time which varied widely between the studies, ranging from 18 to 240 min, with most of the studies reporting mean or median operative times between 60 and 100 min. Six publications reported an operative time >100 min. Aiolfi et al., 2019 informed that operative time ranged from 45 - 180.4 min in the studies evaluated by the meta-analysis. Importantly, the different definition of operative time (e.g. docking and console time, only console time, time spent in the operating theatre, and others) contributes to a higher heterogenicity of data which may affect overall conclusions.

RAS Ahead Study with Dexter

One procedure out of fifty (2%) was permanently converted to laparoscopy at the time of the mesh placements due to the limitation of the workspace area. The surgery was then completed laparoscopically. This workflow was applied to the right and left inguinal hernias. No intra- or post-procedural complications were reported for this patient.

During one procedure for the treatment of a unilateral inguinal hernia, the surgeon switched to the laparoscopic mode during the reduction of the hernia content due to the size of the hernia and difficulties in pulling the hernia sac. Following the mesh placement and fixation, the peritoneal closure and end of the procedure was complete robotically.
The mean reported operative times (skin incision to skin suturing) were 54.5 minutes for unilateral procedures and 94.6 minutes for bilateral procedures.

Conclusion

With a conversion rate of 2%, the rate of permanent conversion to an open or fully laparoscopic surgical approach is comparable to what is being reported in the RWE report and previously cleared robotic systems. The reported rate of permanent conversions is also within the rate of 10% that was defined in the study protocol for the Clinical Acceptance Criteria.
Regarding the operative time, results from the RAS Ahead study obtained a mean operative times of 54.5 minutes for unilateral and 94.6 minutes for bilateral hernias, which is in line with the mean operative time between of 60 to 100 minutes reported in the RWE report.

Complications and Adverse Events

Literature Report:

The use of da Vinci systems in the conduction of IHR was associated with low conversion rates (0 to 4.6%), in which the few reported conversion cases were related either to the experience of the surgeon, anatomical aspects, or other specific clinical characteristics.
The reported complications were mainly mild and moderate (e.g. seroma, hematoma, pain) and reported at different rates (hematoma: 0.25 - 4.1%, seroma: 0.25 - 25.6%, urinary retention: 1.3 - 18%). Nonetheless, the majority of publications reported low rates of intra (<1%) and postoperative (< 5%) complications.

Although the Clavien-Dindo Classification is widely used by the medical and the scientific community to better group complications, only five publications used this classification, in which the majority of the patients were classified as Clavien-Dindo Class I and II (0 - 22%), which are mainly mild and moderate events, which may require more specific medication, blood transfusion or re-hospitalization. More severe complications including Grade III and IV were observed in lower rates (< 6.7%), and no cases of Grade V were reported in patients submitted to rIHR.

Overall, the scientific literature shows that rIHR is characterized by low rates of conversion to open surgery, inguinal hernia recurrence, and complications.

RAS Ahead Study with Dexter as compared to the above literature study.

A total of 12 Adverse Events were reported on the patient population treated within the inguinal hernia study. Adverse Events were adjudicated by a CEC:

Table 77: Perioperative and update 30 days postoperative AEs

	mITT (N= 50)			
	Adverse Events		Serious Adverse Events	
Surgery Type	**# AEs**	**# (%) Subjects**	**# AEs**	**# (%) Subjects**
Anesthesia complications	1	1 (2.0%)	0	0
Hematoma	3	3 (6.0%)	0	0
Other	3	3 (6.0%)	1	1 (2.0%)
Persistent groin pain	1	1 (2.0%)	0	0
Seroma	3	3 (6.0%)	0	0
Trocar-specific complication	1	1 (2.0%)	0	0
Total	12	9 (18.0%) *	1	1 (2.0%)

* The 9 is representative of unique subjects that had a procedure-related event. Two subjects each had 2 procedure- related events which leads to the 11 events in 9 subjects.

No intra-operative Adverse Event was reported. Perioperative and postoperative, hematoma and seroma were the most frequently reported Adverse Events, both with 6% of occurrence. 11 (16%) events were classified as Clavien-Dindo I, only 1 (2%) event (small intestine occlusion) was classified as Clavien-Dindo II. None of the reported Adverse Events were considered as device-related. With respect to the reported three Hematoma:

- None of the reported hematoma required treatment/intervention' 2 out of the 3 hematomas were resolved at study completion.
- Seroma (3x)
- None of the reported seroma required treatment/intervention, all events were ongoing at study completion.
- Persistent groin pain (1x)
- Subject received pain killer medication, event was ongoing at study completion with a VAS of 10mm, which can be considered as mild pain.
- Trocar specific complication – hyperesthesia (1x)
- No treatment/intervention was required, event was ongoing at study completion.
- Anesthesia complication – nausea (1x)
- No treatment/intervention was required, event was resolved at study completion.
- Other Adverse Events (3x)
- 1x small intestine occlusion: subject was re-hospitalized and received medications, event was resolved at study completion.
- 1x erectile dysfunction secondary to hematoma: no treatment/intervention, event was resolved at study completion.
- 1x mild traumatic brain injury caused by a fall on the head: not procedure related, no treatment/intervention, event was resolve7d with sequelae at study completion.
- 100% of the data reported in the RAS Ahead study were source data verified. This might potentially have an impact on the number of reported adverse events compared to the data reported in the RWE, where the data might not be monitored with the same scrutiny and thus have a lower number of reported complications.

Conclusion on Safety and Performance per Literature Report

Intraoperative complications and adverse events were rarely observed with comparative devices. Similar results were obtained with Dexter, where all adverse events occurred in the postoperative phase and no device-related events were reported. Adverse events based on the Clavien-Dindo classification referred to grade I and II for comparative devices, including hematoma, superficial infections, use of analgesics for pain management, or fever. Grade III and IV events only affected few patients. Similar to data from comparative devices, Grade I and II adverse events included hematoma, seroma, or groin pain. None of the study subjects experienced any Grade III and IV complications.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The device user manual and instructions for use include a description of the device technical parameters and instructions for use for the device. The user manual also contains relevant findings from the clinical study with the performance characteristics of the device when used as intended. The document also states the shelf life for any sterile components as well as the necessary measures to properly dispose of any single use items and clean the reusable components of the device.

Labeling also includes the following:

(i) Exclusion parameters for use of the device.

(ii) A detailed summary of the clinical evaluations pertinent to use of the device and accessories; and

(iii) A statement that the device shall only be used by personnel that have been trained in its operation

RISKS TO HEALTH

Table 12 identifies the risks to health that may be associated with use of an electromechanical surgical system with transient sterile field presence of both surgeon and primary control interface.

TABLE 12. RISKS TO HEALTH

Risks to Health	Mitigation Measures
Electrical fault, electromagnetic interference, mechanical fault, or system malfunction resulting in: • Tissue injury	Clinical performance testing Postmarket surveillance Non-clinical performance testing Sterilization validation

Risks to Health	Mitigation Measures
• Electric shock • Prolonged procedure time	Reprocessing validation Annual reporting Electrical safety testing Electromagnetic compatibility testing Software verification, validation, and hazard analysis Cybersecurity testing Thermal effects on tissue testing Labeling
Use error leading to patient harm or prolonged procedure time: • Re-operation • Hematoma • Tissue injury • Increased blood loss	Clinical performance testing Postmarket surveillance Training Annual reporting Human factors testing Labeling
Infection	Clinical performance testing Postmarket surveillance Human factors testing Non-clinical performance testing Sterilization validation Reprocessing validation Biocompatibility testing Shelf-life validation Pyrogenicity testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, Electromechanical surgical system with transient sterile field presence of both surgeon and primary control interface is subject to the following special controls.

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance conducted per a protocol approved by FDA and acquired under anticipated conditions of use must demonstrate that the device performs as intended in the intended patient population, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required.
   (i) Data provided from (1) must demonstrate the performance of the device for providing accurate and precise control of attached surgical instruments in a variety of disease etiologies relevant to the device intended use. The test data set must include data acquired from a patient population that is representative of the intended patient population.

(ii) Objective performance measures (e.g., rate and number of conversions to open or fully laparoscopic surgery, rate of device related adverse events and their severity, cause, and outcomes) must be reported with relevant descriptive or developmental performance measures.

(2) The device manufacturer must develop, and update as necessary, a device-specific use training program that ensures proper device setup/use/shutdown, accurate control of instruments to perform the intended surgical procedures, troubleshooting and handling during unexpected events or emergencies, and safe practices to mitigate use error.

(3) The device manufacturer may only distribute the device to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program.

(4) Human factors validation testing must be performed and must demonstrate that the device/user interfaces of the system support safe use in all use environments, including the effect on procedure workflow of the movement of the operator between the patient bedside and the user console.

(5) Labeling must include:

(i) A detailed summary of clinical performance testing conducted with the device, including study population, results, adverse events, and comparisons to any comparator groups identified;

(ii) A statement in the labeling that the safety and effectiveness for the representative-specific procedures was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of the patient's underlying disease or condition, unless FDA determines that it can be removed or modified based on clinical performance data submitted to FDA;

(iii) Identification of compatible devices;

(iv) The list of surgical procedures for which the device has been determined to be safe with clinical justification;

(v) Reprocessing instructions for reusable components;

(vi) A shelf life for any sterile components;

(vii) A description of the device-specific use training program;

(viii) A statement that the device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program; and

(ix) A detailed summary of the post-market surveillance data collected under paragraph (1) of this section and any necessary modifications to the labeling to accurately reflect outcomes based upon the post-market surveillance data collected under paragraph (1) of this section.

(6) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:

(i) Device motion accuracy and precision;

(ii) System testing;

(A) Instrument reliability;

(B) Thermal effects on tissue;

(C) User-device interface performance;

(D) Patient/device interface bumping and tipping hazards;

(E) Workspace access testing; and

(F) Performance testing with compatible devices.

(7) Software verification, validation, and hazard analysis must be performed.
(8) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.
(9) Performance data must demonstrate the sterility of all patient-contacting device components.
(10) Performance data must support the shelf life of the device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.
(11) Performance data must validate the reprocessing instructions for the reusable components of the device.
(12) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.
(13) Performance data must demonstrate that all patient-contacting components of the device are non-pyrogenic.
(14) The device manufacturer must submit a report to the FDA annually on the anniversary of initial marketing authorization for the device, until such time as FDA may terminate such reporting, which comprises the following information:
    (i) Cumulative summary, by year, of complaints and adverse events since date of initial marketing authorization; and
    (ii) Identification and rationale for changes made to the device, labeling, or device-specific use training program, which did not require submission of a premarket notification during the reporting period.

BENEFIT-RISK DETERMINATION

The risks of the device are based on nonclinical laboratory as well as data collected in the clinical studies described above.

Based on other robotically assisted surgical devices and the risk analysis of the subject device, several risks of the Dexter L6 Surgical System have been identified, including:

1. Robot-related risks
- Thermal, electrical, or mechanical fault, or system malfunction resulting in patient injury
- User error resulting in patient injury
- Adverse tissue reaction
- Infection
- Bleeding

For the Proposed Indications for Use

2. General risks related to the laparoscopic operative procedure
- Anesthesia
- Trocar injuries
- Electrical burns from electrodes
- Insufflation-related risks (PE, thromboembolic event)

Clinical study population had limited representation in co-morbidities, minority ethnic groups. This contributes to risk uncertainty.

The probable benefits (e.g. the reduced time for the surgeon to get to the patient if needed) of the device are also based on nonclinical laboratory and data collected in the clinical studies as described above.

The probable benefits of the Dexter L6 System have been demonstrated in the RAS Ahead study performed for inguinal hernia repair in support of this De Novo. 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 49 of 50 procedures (98.0%). The reported rate of conversions is within the rate of 10% that was defined in the study protocol for the Clinical Acceptance Criteria. There were no postoperative serious (Clavien-Dindo grades III-V), device-related adverse events perioperatively up to 30 days. Overall, subjects experienced a short return to normal activities and a significant reduction in pain at 30 days.

The benefits are further demonstrated in the commercial experience of the device in the EU. Of the 639 commercial procedures completed across 3 surgical specialties (general, gynecologic, urologic) representing 35 individual procedure types (including inguinal hernia n=178), only 1 conversion (0.16%) (total hysterectomy) occurred. The interim Post-Market Clinic Follow-up (PMCF) study report showed an overall procedural success rate of 94.9% with the Dexter L6 System in all indications.
The rate of conversion to an open or fully laparoscopic surgical approach is comparable to what has been reported in the RWE report of other robotic surgical systems and is well below the expected ~ 10% rate.

Regarding the operative time, results from the RAS Ahead study obtained a mean operative times of 54.5 minutes for unilateral and 94.6 minutes for bilateral hernias, which is in line with the mean operative time between of 60 to 100 minutes reported in the RWE report of other robotic surgical systems.

The RAS Ahead study also demonstrated a favorable safety profile for the Dexter L6 System. No device-related adverse event was observed perioperatively up to 30 days in the pivotal clinical study. All complications observed in the pivotal study were Clavien-Dindo grade I or II, and none of the study subjects experienced any Grade III and IV complications. These results are similar to the findings based on the RWE report of other robotic surgical systems.
Based on the study design and execution, as well as other clinical experience with the device due to its EU commercial distribution, the degree of uncertainty in terms of either benefit or risk is low.

The RAS Ahead study was conducted as a prospective, protocol-driven and monitored study. All adverse events were reviewed by a Clinical Events Committee (CEC). The high % of white males was similar to reports in the published literature. However, to address uncertainty regarding any variation in outcomes due to race or gender, the sponsor will study the first 100

subjects in the USA in a post approval study out to 1 year follow up. We believe this will reduce uncertainty regarding race and gender concerns. Further, there was little variation in the surgeon experience, there was no data on recurrent hernias and the BMI range of patients in the study was on the low end of the US population (<40). Therefore, to address outstanding uncertainties for surgeon training and experience, and in these patient populations, the post approval study will be conducted to mitigate the differences in US and OUS surgeon training, and differences in US and OUS patient populations. In addition, the RAS Ahead study only included 3 surgeons with 9 months - 5 years of robotic experience which may not completely be representative of a diverse population of surgeons in the USA. Specifically, we are unsure if an experienced daVinci surgeon would experience any negative transference with this device.

While the study provided was not statistically powered, sample size of 50 is in line with clinical studies supporting other robotic surgery systems. The clinical study results for the Dexter L6 System were also compared to the performance of other robotic surgical systems as reported in the published literature with comparable results.

PATIENT PERSPECTIVES

This submission did not include specific information on patient perspectives for this device.

BENEFIT/RISK CONCLUSION

In summary, based on the available information above, the Dexter L6 Surgical System has both benefits and risks for the following indication statement:

> 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, dissecting, coagulating and cutting, with or without high frequency functionality. The Distalmotion Dexter L6 System is intended for use in laparoscopic inguinal hernia repair. The system is indicated for adult uses, as defined as 22 years old and older. It is intended for use by trained laparoscopic 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.

Use of the Dexter L6 device will provide an alternative method for patients to undergo inguinal hernia repair procedures safely and effectively. This device increases access to minimally invasive surgery for patients who do not have access with current robotic and minimally invasive technologies. Well-established benefits of minimally invasive procedures compared to open procedures include low surgical site occurrence/infection rates, low blood loss leading to reduced blood transfusion rates, and low hospital length of stay.

The Dexter L6 Surgical System operates using similar principles as other robotically assisted surgical devices, but it allows for the surgeon and the user interface to be in the sterile field, as compared to other approved, or granted devices. Additionally, the surgical steps and techniques

used for inguinal hernia repair are identical to other robotic and laparoscopic approaches and therefore carry the same level of risk as traditional inguinal hernia repair procedures including open, laparoscopic, or robotic.

The risks of this novel device include risks seen with other RASD platforms such as uncontrolled or uncoordinated instrument movement causing inadvertent patient harm which can be due to software or hardware failures. There are risks of infection due to sterility concerns and tissue damage from biocompatibility concerns from the tissue contacting portions of the device. Many of these risks have been mitigated with adequate validation and verification testing and are therefore low risks with low uncertainty. Poor device effectiveness is a risk, which may result in a prolonged operation, but it was not seen in the 50 subject studies conducted with the device in France, Switzerland, and Germany. The device has shown high efficacy in the studies with a comparable safety profile to the comparator studies and there is sufficient evidence to substantiate a benefit to patients who may receive care with the device.

However, there is some uncertainty associated with the Dexter L6 surgical system. Each study enrolled only 50 subjects, had a small number of surgeons with low variability of experience, and each was conducted outside the US. Low subject BMI in comparison to the US population and the lack of racial data for detailed comorbidity evaluation increase uncertainty on how the system will perform in the targeted US population. Only 3 surgeons were included in the studies, and it is not clear if they had used RASDs common in the US market. The low number of surgeons and OUS study design increase uncertainty of both benefits (possible reduction in mean op time and surgeon training time) and risks (negative transfer). A postmarket surveillance special control study (PSSC) will be conducted to mitigate uncertainty arising from the low subject number, surgeon learning curve, differences in US and OUS surgeon training, and differences in US and OUS patient populations.

With the PSSC in mind, the probable benefits outweigh the probable risks for the Dexter L6 Surgical System. The device provides benefits and the risks can be mitigated using general controls and the identified special controls.

CONCLUSION

The De Novo for the Dexter L6 Surgical System is granted and the device is classified as follows:

Product Code: 21 CFR 878.4965

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

Regulation Number: SDD

Class: II