December 4, 2025

Covidien, LLC
Tamar Jaghasbanian
Director Regulatory Affairs
60 Middletown Ave.
North Haven, Connecticut 06473

Re: K250725
Trade/Device Name: Hugo™ RAS System
Regulation Number: 21 CFR 878.4964
Regulation Name: Modular electromechanical surgical system
Regulatory Class: Class II
Product Code: SCV

Dear Tamar Jaghasbanian:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 4, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter to correct the official correspondent as an administrative correction and to correct a typo in the device trade name.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark Trumbore, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 301-796-5436, Mark.Trumbore@fda.hhs.gov.

Sincerely,

Mark Trumbore -S

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

December 3, 2025

Covidien LLC
Shriya Kafle
Principal Regulatory Affairs Specialist
60 Middletown Ave
North Haven, Connecticut 06473

Re: K250725
Trade/Device Name: Hugo RAS System
Regulation Number: 21 CFR 878.4964
Regulation Name: Modular Electromechanical Surgical System
Regulatory Class: Class II
Product Code: SCV
Dated: October 31, 2025
Received: November 3, 2025

Dear Shriya Kafle:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 and the October 11, 2024 De Novo classification order for this device type. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Per the October 11, 2024 De Novo classification order for this device type, you must demonstrate that the device performs as intended under anticipated conditions of use in the intended patient population. The special control requirements set forth in that order include initiation, enrollment, completion, and reporting requirements associated with any required postmarket surveillance. Within 30 days of receipt of this letter, you must submit a complete study protocol for a postmarket surveillance study consistent with the special control requirements. FDA expects to work with you to approve your study protocols within 60 days of this letter. Your submission should be clearly labeled as "Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the 510(k) number above to facilitate processing. If there are multiple protocols being finalized after clearance of this510(k) submission, please submit each protocol as a separate submission, identified by their unique study name(s).

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

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

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

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

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve

changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Postmarket Mandated Studies Program
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2025.12.03 13:16:14 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250725

Device Name
Hugo™ RAS System

Indications for Use *(Describe)*
The Hugo™ Robotically Assisted Surgery (RAS) System is intended to assist in the accurate control of instruments and accessories including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/graspers, needle holders, electrosurgical tools and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, and suturing during minimally invasive urologic surgical procedures. The system is indicated for adult use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative surgical procedures set forth in the Hugo™ RAS System Indications Document.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K250725

1. Submitter

510(k) Submitter:	Covidien LLC
Address:	60 Middletown Ave. North Haven, CT 06473 USA
Contact Person and Information:	Tamar Jaghasbanian Director Regulatory Affairs e-mail: tamar.t.jaghasbanian@medtronic.com
Date Summary Prepared:	December 2, 2025

2. Subject Device Information

Manufacturer Name:	Covidien LLC
Trade Name:	Hugo™ RAS System
Common Name:	System, surgical, computer-controlled instrument
Classification Name:	General & Plastic Surgery (21 CFR 878.4964)
Regulatory Class:	Class II
Product Code:	SCV
Regulation Name:	Modular Electromechanical Surgical System
Submission Type:	Traditional 510(k)

3. Predicate Device Information

Manufacturer Name:	CMR Surgical Limited
DeNovo Approval Number:	DEN230078
Trade Name:	Versius Surgical System
Classification Name:	General & Plastic Surgery (21 CFR 878.4964)
Regulatory Class:	Class II
Product Code:	SCV
Submission Type:	Modular Electromechanical Surgical System

4. Device Description

The Hugo™ RAS System is a modular assembly of devices intended to assist a surgeon with the accurate control of instruments and accessories for performing tele- operative surgical procedures. It is a system of software-operated, electro-mechanical, cable-connected capital equipment with compatible instruments and accessories.

The major components of the Hugo™ RAS System are capital equipment: (1) System Tower, (2) Surgeon Console, and (3) Arm Cart Assemblies (ACAs). Each Arm Cart Assembly (ACA) consists of a movable cart with casters supporting setup arm connected to a modular and extendable robotic arm containing an instrument drive unit (IDU). Instruments and accessories attach to the IDUs of the robotic arms to perform robotically assisted surgery. The Surgeon Console is the surgeon's interface for controlling the Hugo RAS System. The Surgeon Console is operated by the user to control the robotic arms and attached instruments. The System Tower is a mobile cart that houses system computers, high-definition operating room team interactive (ORTI) display, power-management system and cable hooks for cable storage.

Hugo™ RAS system instruments include wristed instruments enabling surgeons to precisely grab, dissect, manipulate and suture tissue. There are nine different wristed instruments currently part of the Hugo™ RAS System grouped into basic instruments and electrosurgical instruments, including Large Needle Driver, Extra Large Needle Driver, Double Fenestrated Grasper, Toothed Grasper, Cadiere Forceps, Secure Cadiere Forceps, Monopolar Curved Shears, Bipolar Maryland Forceps and Bipolar Fenestrated Grasper. Hugo™ RAS system accessories include 3D glasses, surgical drapes, Endoscope Adapters, Sterile Interface Modules, Instrument Key, and Monopolar Tip Covers. These accessories enable the Hugo™ RAS system and instruments to achieve their intended use.

5. Indications for Use

The Hugo™ Robotically Assisted Surgery (RAS) System is intended to assist in the accurate control of instruments and accessories including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/graspers, needle holders, electrosurgical tools and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, and suturing during minimally invasive urologic surgical procedures. The system is indicated for adult use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative surgical procedures set forth in the Hugo™ RAS System Indications Document.

6. Comparison of Technological Characteristics with the predicate device

The Hugo RAS System and the Versius Surgical System which is the legally marketed predicate device under DeNovo approval letter DEN230078 have the same intended use and similar technological characteristics. A summary of the technological characteristics of the subject device compared to the predicate device is provided below:

Table 1: Summary of the technological characteristics of the subject device compared to the predicate device

Technological Characteristics	Hugo RAS system (Subject device)	Versius Surgical System (Predicate Device)
Intended and Indications for Use	The Hugo™ Robotically Assisted Surgery (RAS) System is intended to assist in the accurate control of instruments and accessories including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/graspers, needle holders, electrosurgical tools and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, and suturing during minimally invasive urologic surgical procedures. The system is indicated for adult use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative surgical procedures set forth in the Hugo™ RAS System Indications Document.	The Versius Surgical System is a robotically assisted surgical device that is intended to assist in the precise and accurate control of Versius Surgical endoscopic instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps/pick-ups, needle holders, electrosurgery, and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery and suturing. The Versius Surgical System is indicated for adult patients 22 years of age and older, eligible for soft tissue minimal access surgery, for cholecystectomy.
Environment Used	Operating Room Operating conditions: Temperature (°C) - 10 to 30 Operating conditions: Humidity (%) - 30 to 75 (non- condensing) Operating conditions: Pressure (hPa) - 700 to 1060	Operating Room Operating conditions: Temperature (°C) - 15 to 27 Operating conditions: Humidity (%) - 30 to 75% (non- condensing) Operating conditions: Pressure (hPa) - 700 to 1060
Main System Components	Up to 4 Arm Carts (Endoscope or Instrument interchangeable) Surgeon Console (outside sterile field) System Tower (incl. Karl Storz 3D Endoscope and Vision System or Rubina System; Covidien ValleyLab FT10 Electrosurgical Generator)	Up to 4 Arm Carts (with one being a dedicated Endoscope Arm) Surgeon Console (outside sterile field)
Patient Cart	Modular	Modular

Technological Characteristics	Hugo RAS system (Subject device)	Versius Surgical System (Predicate Device)
Architecture		
Console Architecture	Open	Open
Degrees of freedom	7	7
Mechanism of Action	Electromagnetically Actuated Joints	Electromagnetically Actuated Joints
Reach/Range of Motion	510 degrees of robotic arm range of motion	Internal Reach: 710deg
Remote Center of Motion / Fulcrum	Fixed mechanical remote center of motion; by attaching to compatible port, system determines remote center of motion	Software remote center of motion set by user through “Port Training” steps in User Manual
Registration to Patient Orientation	The User registers the orientation of the patient during patient positioning for each Arm Cart to ensure all Arms are moving in the same plane of motion.	The system needs to know the orientation of each bedside unit to ensure that the instruments and endoscopic camera move in the correct directions. The orientation is set after the bedside unit is draped and positioned next to the operating table and the brake is activated. To ensure that the orientations of all bedside units are set correctly, the User chooses a reference direction such as the ’12 o’clock’ direction and registers each bedside unit’s plane of motion.
Collision Detection	An alarm sounds is made when the unit detects an arm collision that could occur manually or under teleoperation	An alarm sound is made when the unit detects an arm collision that could occur manually or under teleoperation
Surgeon Control - Instruments	Pistol-like handle Hand detection (safety mechanism)	Joystick handle controls Hand detection (safety mechanism)
Instruments & Compatibility	Wristed Instruments: Monopolar Curved Shears, Bipolar Fenestrated Grasper, Bipolar Maryland Forceps, Large Needle Driver, Extra Large Needle Driver, Secure Cadiere Forceps, Cadiere Forceps, Double Fenestrated Grasper, Toothed Grasper Hugo Instruments only compatible with VersaOne Positioning Trocar System or	Wristed Instruments: Needle Holder, Bipolar Maryland Grasper, Fenestrated Grasper, Monopolar Hook, Curved Scissors, Monopolar Curved Scissors Versius Instruments Compatible with **5 mm** Applied Medical balloon ports[1].

Technological Characteristics	Hugo RAS system (Subject device)	Versius Surgical System (Predicate Device)
	VersaOne Reusable Positioning Trocar System (**8mm or 11mm**)	
Sterility	Reusable instruments not shipped sterile. Single-Use (Packaged Sterile): Drapes and Instrument Tip Cover Sterilization method ISO 11135 Ethylene Oxide ISO 17665-1 Moist Heat ISO 11607-1 & -2 Sterile Packaging ISO 11737-1 & -2 Microbio Methods Surgeon is not sterile during procedure.	Reusable instruments not shipped sterile. Sterile Drape Bedside unit & camera head drapes, no instrument tip cover Sterilization method: ISO 17665-1 Moist Heat Non-sterile packaging Surgeon is not sterile during procedure.
Reprocessing	Reprocessing process: point of use pre-treatment, preparation for cleaning, manual cleaning, inspection, sterilization Standard: In compliance with ISO 17665-1 and ISO 17664-1 Parameters (Ultrasonic cleaning): Frequency: 40 kHz Power: 280 Watts Time: 20-40 minutes Temperature: 32-40̊ C (90-104°F) Parameters (prevacuum steam sterilization): Temperature: 132°C (270°F)) Exposure time: 4 minutes Dry time: 20 minutes (minimum) Temperature: 135°C (275°F)) Exposure time: 3 minutes Dry time: 16 minutes (minimum)	Reprocessing process: point- of-use preparations, initial manual cleaning, main cleaning (includes manual cleaning, ultrasonic cleaning, or automated cleaning and thermal disinfectant), preparation for sterilization, and sterilization Standard: In compliance with ISO 17665-1 Parameters (Ultrasonic cleaning): Frequency: 40 kHz ± 2.4 kHz Performance: 15 W/L (57 W/gal) or greater Time: 10 minutes (minimum) Parameters (prevacuum steam sterilization): Temperature: 134–137 °C (273–279°F) Exposure time: 3–18 minutes (minimum holding time) Dry time: 20 minutes (minimum)
Surgeon Control - Camera	The input devices (camera foot pedal and hand controllers) are utilized to move and zoom the camera when in camera control mode. Head tracking of the User 3D Glasses disables any motion (Endoscope or Instrument) if the Surgeon is looking off-screen.	Versius Endoscopic Camera consists of a Versius Camera Head and endoscope. The endoscopic camera can be controlled with a thumb stick on a hand controller if: The endoscopic camera is attached to the visualization arm The visualization arm is in surgical mode

Technological Characteristics	Hugo RAS system (Subject device)	Versius Surgical System (Predicate Device)
		The hand controller is engaged to an arm
Compatible Vision System & Endoscope	Karl Storz 10mm SPIES 3D Endoscope (0° and 30°) Light Source: Storz TL300 Karl Storz 10mm TIPCAM1 Rubina Video Endoscope System (0° and 30°) with ICG capability Light Source: Storz TL400	10mm 3D HD Endoscope (0° and 30°) (Richard Wolf Panoview) Wolf Endolight LED 2.2 light source & Brand Model Stryker L9000 Stryker L10 AIM Stryker L11 Stryker Precision Olympus CLV-190 Storz TL-300 Storz TL400 Storz D-light P B-Braun OP950
Compatible Electrosurgical System	Covidien ValleyLab FT10 Electrosurgical Generator (Integrated onto Hugo Tower)	Not specified in User Manual, but includes Covidien ValleyLab FT10 Electrosurgical Generator
Surgeon Control – Electrosurgical Activation	Foot pedals on Surgeon Console, one dedicated per energy type. Compliant with IEC 60601-2-2 HiFreq Surgical Equipment	No foot pedal controls, all functions are managed by joystick controllers (including electrosurgical activation) The electrosurgery mode indicator (next to electrosurgery button) provides an LED color indicating the mode to which the instrument is set: yellow for cut and blue for coagulation. Electrosurgical Unit not supplied with Versius system. Compliant with IEC 60601-2-2 HiFreq Surgical Equipment
Software and Cybersecurity	Software and cybersecurity documentation is in accordance with “Content of Premarket Submissions for Device Software Functions, Issued June 2023” and FDA guidance on "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"	Software and cybersecurity documentation is in accordance with “Content of Premarket Submissions for Device Software Functions, Issued June 2023” and FDA guidance on "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"
Safety Features	Hand & Eye Detection Required for Instrument Control Direct bedside input prioritized over surgeon input and required for bedside motion Instrument movement rotates around a center of motion relative to the port Preventative measures against tipping	Hand detection required for Instrument Control Direct bedside input required for bedside motion Instrument movement rotates around a center of motion relative to the port Emergency Stop of motion Essential information, alerts & alarms to

Technological Characteristics	Hugo RAS system (Subject device)	Versius Surgical System (Predicate Device)
	System safety-controlled stop of motion Essential information, alerts, & alarms to perform surgery User input constantly required to move robot arms Collision and Stability Safety Measures	perform surgery User input constantly required to move robot arms Collision and Stability Safety Measures
Accuracy and Motion	Instrument motion accuracy demonstrated by the accuracy of the surgical instruments and amount of unintended motion when under surgeon control.	Instrument motion accuracy demonstrated by the accuracy of the surgical instruments and amount of unintended motion when under surgeon control.

7. Summary of Performance Data

The Hugo™ RAS system is in conformance with the Special Controls specified for product code SCV, ensuring substantial equivalence between the subject and predicate devices. The following non-clinical performance testing was performed to demonstrate that the Hugo™ RAS system is safe and effective and performs as intended:

a. Animal Testing
b. Human Factors Validation
c. Bench Testing (including Motion Accuracy and System Testing)
d. Software Testing
e. Electromagnetic compatibility and electrical, thermal, and mechanical safety testing
f. Sterility Testing
g. Shelf-Life Testing
h. Reprocessing Validation
i. Biocompatibility and Pyrogenicity testing

7.1 Clinical Data

A prospective, multi-center, non-randomized single-arm study evaluating the safety and effectiveness of the Hugo RAS system in urologic robotic-assisted surgery (RAS) procedures was conducted (the Expand URO study). This study evaluated treatment of 137 subjects undergoing cystectomy (n=29), nephrectomy (n=53), and prostatectomy (n=55) at six investigational sites in the United States. Data was collected on all subjects through 30 days post-procedure.

Baseline Demographics and Medical History (Treated Subjects)
Subject demographics and medical history were collected at the baseline visit for subjects and are listed in the tables below.

Table 2: Baseline Demographics

Subject Characteristics	Cystectomy (N=29)	Nephrectomy (N=53)	Prostatectomy (N=55)	Total (N=137)
Age (years)				
Mean (SD)	68.9 (9.24)	61.2 (10.32)	62.9 (6.70)	63.5 (9.19)
Sex, n (%)				
Male	26 (89.7%)	33 (62.3%)	55 (100.0%)	114 (83.2%)
Female	3 (10.3%)	20 (37.7%)	0 (0.0%)	23 (16.8%)
Weight (kg)				
Mean (SD)	87.9 (20.10)	89.3 (20.24)	87.9 (16.70)	88.5 (18.74)
Height (cm)				
Mean (SD)	173.6 (10.24)	173.5 (10.21)	177.5 (7.05)	175.1 (9.22)
BMI (kg/m2)				
Mean (SD)	29.3 (6.51)	29.6 (6.25)	27.9 (5.04)	28.9 (5.86)
ASA Score, n (%)				
ASA I	0 (0.0%)	1 (1.9%)	1 (1.8%)	2 (1.5%)
ASA II	3 (10.3%)	15 (28.3%)	18 (32.7%)	36 (26.3%)
ASA III	25 (86.2%)	36 (67.9%)	36 (65.5%)	97 (70.8%)
ASA IV	1 (3.4%)	1 (1.9%)	0 (0.0%)	2 (1.5%)
ASA V	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Race, n (%)				
White	20 (69.0%)	31 (58.5%)	42 (76.4%)	93 (67.9%)
Black or African American	4 (13.8%)	14 (26.4%)	7 (12.7%)	25 (18.2%)
Asian	2 (6.9%)	5 (9.4%)	1 (1.8%)	8 (5.8%)
Other	3 (10.3%)	3 (5.7%)	5 (9.1%)	11 (8.0%)
Ethnicity, n (%)				
Not Hispanic Or Latino	19 (65.5%)	36 (67.9%)	44 (80.0%)	99 (72.3%)
Not Reported	8 (27.6%)	15 (28.3%)	7 (12.7%)	30 (21.9%)
Hispanic Or Latino	2 (6.9%)	2 (3.8%)	4 (7.3%)	8 (5.8%)

Table 3: Medical History

Medical History, % Subjects (n/N)	Cystectomy (N=29)	Nephrectomy (N=53)	Prostatectomy (N=55)	Total (N=137)
Diabetes	31% (9/29)	26.4% (14/53)	18.2% (10/55)	24.1% (33/137)
Coronary Artery Disease	17.2% (5/29)	18.9% (10/53)	12.7% (7/55)	16.1% (22/137)
Hypertension	79.3% (23/29)	62.3% (33/53)	54.5% (30/55)	62.8% (86/137)
Cerebral Vascular Accident	3.4% (1/29)	7.5% (4/53)	1.8% (1/55)	4.4% (6/137)
Transient Ischemic Attack	0% (0/29)	3.8% (2/53)	0% (0/55)	1.5% (2/137)
Clotting Disorder	10.3% (3/29)	0% (0/53)	0% (0/55)	2.2% (3/137)
Thrombocytopenia	0% (0/29)	0% (0/53)	1.8% (1/55)	0.7% (1/137)
Anemia	20.7% (6/29)	15.1% (8/53)	10.9% (6/55)	14.6% (20/137)
Anxiety	6.9% (2/29)	13.2% (7/53)	10.9% (6/55)	10.9% (15/137)
Depression	6.9% (2/29)	13.2% (7/53)	12.7% (7/55)	11.7% (16/137)
Hyperthyroidism	0% (0/29)	0% (0/53)	0% (0/55)	0% (0/137)
Hypothyroidism	17.2% (5/29)	15.1% (8/53)	12.7% (7/55)	14.6% (20/137)
Kidney Infection	3.4% (1/29)	3.8% (2/53)	0% (0/55)	2.2% (3/137)
Benign Prostatic Hyperplasia*	34.6% (9/26)	9.1% (3/33)	9.1% (5/55)	14.9% (17/114)
Erectile Dysfunction*	7.7% (2/26)	18.2% (6/33)	32.7% (18/55)	22.8% (26/114)
Urinary Frequency	20.7% (6/29)	1.9% (1/53)	10.9% (6/55)	9.5% (13/137)
Urinary Incontinence	3.4% (1/29)	5.7% (3/53)	0% (0/55)	2.9% (4/137)
Urinary Retention	13.8% (4/29)	0% (0/53)	1.8% (1/55)	3.6% (5/137)
Fecal Incontinence	0% (0/29)	1.9% (1/53)	1.8% (1/55)	1.5% (2/137)
Cancer	100% (29/29)	39.6% (21/53)	100% (55/55)	76.6% (105/137)
Other Relevant Medical History	48.3% (14/29)	60.4% (32/53)	74.5% (41/55)	63.5% (87/137)
Previous Intra-abdominal Surgeries	62.1% (18/29)	34% (18/53)	32.7% (18/55)	39.4% (54/137)

Note: A subject may have more than one medical history.
*Applicable to male subjects only.

Primary Safety and Effectiveness Clinical Study Results

The study was successful meeting both the primary safety and effectiveness endpoints.

Table 4: Clinical Study Results

Endpoint/Cohort		Study Result	Performance Goal	P-value
Primary Effectiveness - Surgical Success	Combined Across Cohorts	98.50% (134/136)	85.00%	<0.0001*
Primary Safety - Major Complications (CD ≥ III) within 30 days	Cystectomy	17.9% (5/28)	40.00%	0.0025**
Primary Safety - Major Complications (CD ≥ III) within 30 days	Nephrectomy	1.9% (1/52)	20.00%	0.0083**
Primary Safety - Major Complications (CD ≥ III) within 30 days	Prostatectomy	3.7% (2/54)	20.00%	0.0125**

*P-values from binomial exact test. P-value statistically significant at α=0.025, one-sided.
** P-values are from binomial exact test. All p-values are statistically significant at their respective Holm adjusted α, one-sided.

Additional Safety and Effectiveness Results – Key Secondary Endpoints

Secondary endpoints have been included in the summary below.

Key Secondary Endpoints Results:

- Overall Complication rate (≥ CD I within 30 days) was 82.8%, 46.2% and 56.4% for Cystectomy, Nephrectomy and Prostatectomy, respectively. CD = Clavien-Dindo Classification; 73.7% of CD I/II events were reported as having resolved within a median follow-up of 36 days.
- The mean operative time (mins) was 357.8 (SD 83.26), 178.7 (SD 69.52) and 227.8 (SD 54.01) for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- The mean Intraoperative estimated blood loss (mL) was 394.7 (SD 380.29), 117.5 (SD 122.45) and 161.5 (SD 89.34) for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- The transfusion rate was 31.0%, 1.9%, and 0.0% for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- The rate of device related conversion was 0.0%, 1.9% and 0.0% for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- The mean hospital length of stay (days) was 5.4 (SD 2.48), 1.7 (SD 1.53) and 1.2 (SD 0.9), for Cystectomy, Nephrectomy and Prostatectomy, respectively.

  Two outliers in Cystectomy cohort were identified as being greater than 3 standard deviations from the mean and were removed from the analysis.
- The Readmission rate (through 30 days) was 20.7%, 7.5% and 3.6% for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- The Reoperation rate (through 30 days) was 10.3%, 1.9%, and 0.0% for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- The Mortality rate (through 30 days) was 3.4%, 0.0% and 1.8% for Cystectomy, Nephrectomy and Prostatectomy, respectively.

  There was no intraoperative death; 2 deaths occurred in the study, both within 30 days of the study procedure and not related to the study device.
- The device deficiency rate was 69.0%, 54.7%, and 65.5% for Cystectomy, Nephrectomy and Prostatectomy, respectively.

  There were no device related deaths and adverse events were similar to those reported in literature.

Additional Safety Results – Serious Adverse Events

A summary of the serious adverse events that occurred within 30 days of the index procedure is presented below alongside a breakdown of the Clavien-Dindo grades of each.

Table 5: Expand URO Safety Results – Serious Adverse Events

Summary, Events (n/N, %)	Cystectomy	Nephrectomy	Prostatectomy	Total
All Serious Adverse Events (SAE)	48 (15/29, 51.7%)	11 (7/53, 13.2%)	5 (5/55, 9.1%)	64 (27/137, 19.7%)
Clavien–Dindo Grade				
Grade I	8 (5/29, 17.2%)	5 (4/53, 7.5%)	2 (2/55, 3.6%)	15 (11/137, 8%)
Grade II	23 (12/29, 41.4%)	3 (2/53, 3.8%)	1 (1/55, 1.8%)	27 (15/137, 10.9%)
Grade III	5 (4/29, 13.8%)	2 (1/53, 1.9%)	1 (1/55, 1.8%)	8 (6/137, 4.4%)
Grade IIIa	1 (1/29, 3.4%)	2 (1/53, 1.9%)	1 (1/55, 1.8%)	4 (3/137, 2.2%)
Grade IIIb	4 (3/29, 10.3%)	0 (0/53, 0%)	0 (0/55, 0%)	4 (3/137, 2.2%)
Grade IV	10 (3/29, 10.3%)	0 (0/53, 0%)	0 (0/55, 0%)	10 (3/137, 2.2%)
Grade IVa	4 (2/29, 6.9%)	0 (0/53, 0%)	0 (0/55, 0%)	4 (2/137, 1.5%)
Grade IVb	6 (2/29, 6.9%)	0 (0/53, 0%)	0 (0/55, 0%)	6 (2/137, 1.5%)
Grade V	1 (1/29, 3.4%)	0 (0/53, 0%)	1 (1/55, 1.8%)	2 (2/137, 1.5%)
Non-Gradeable Event*	1 (1/29, 3.4%)	1 (1/53, 1.9%)	0 (0/55, 0%)	2 (2/137, 1.5%)

*Non-gradeable events: Adverse events which occurred and were completely resolved within the intraoperative period, with no subsequent postoperative impact.

7.2 Comparator Group

To contextualize the performance of the Hugo™ Robotic-Assisted Surgery (RAS) system within the current urology domain a literature search and accompanying meta-analyses were conducted. This began with a quantitative evaluation of clinical data from recently published literature on RAS procedures in urology that was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Clinical data were obtained from peer-reviewed publications identified through a systematic literature review (SLR) conducted from January 1, 2018, to June 4, 2025. The search focused on the competitive RAS platforms (e.g., Da Vinci, Dexter, Revo, Versius, Senhance) utilized globally in cystectomy, nephrectomy, and prostatectomy procedures.

The literature search of competitive RAS devices identified 202 articles appropriate for inclusion for the purpose of providing information on performance characteristics of existing RAS systems across varied clinical endpoints. From this body of clinical literature, relevant data were extracted for cystectomy, nephrectomy, and prostatectomy procedures and evaluated in subsequent random effects meta-analyses. These meta-analyses informed summaries of SLR rates (means and proportions) and associated 95% or 99% prediction intervals.

Primary Endpoints

- There were 171 literature-based cohorts reporting conversion across all three surgery groups (Cystectomy, Nephrectomy and Prostatectomy), from which the systematic literature review (SLR) rate for conversion was 1.78% with an associated 95% prediction interval (PI) of (0.23%, 12.60%) and 99% prediction interval of (0.12%, 21.85%).
- The SLR rate of major complications (CD Grade ≥ III) through 30 days was 16.03% (95% PI:(5.67%, 37.73%), 99% PI:(3.51%, 50.08%)) from 10 cohorts for Cystectomy, 2.95% (95% PI:(2.47%, 3.54%), 99% PI:(2.30%, 3.79%)) from 15 cohorts for Nephrectomy, and 2.74% (95% PI:(0.41%, 16.10%), 99% PI:(0.20%, 28.21%)) from 18 cohorts for Prostatectomy.

Secondary Endpoints

- The rate of all complications was measured in 11, 35, and 64 literature-based cohorts for Cystectomy, Nephrectomy and Prostatectomy, respectively. SLR rates were 44.97% (95% PI:(14.46%,79.80%) for Cystectomy, 10.53% (95% PI:(3.54%, 27.39%)) for Nephrectomy and 7.92% (95% PI:(1.26%, 36.75%)) for Prostatectomy. The performance targets were 85.0%, 30.0%, and 45.0% for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- Operative times across the literature were observed to have a SLR mean of 299.98 min (95% PI:(34.65, 1021.69)) from 14 cohorts for Cystectomy, 163.88 min (95% PI:(80.58, 289.51)) from 47 cohorts for Nephrectomy, and from 76 literature cohorts within Prostatectomy an SLR average of 186.00 min (95% PI:(97.49, 307.57) was observed. The performance targets were 500 min, 255 min, and 340 min for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- Intraoperative blood loss was observed to have an SLR average of 232.55 mL (95% PI:(54.47, 747.96)) for Cystectomy (15 cohorts), 154.37 mL (95% PI:(32.80, 416.53)) from 47 cohorts for Nephrectomy, and 187.82 mL (95% PI:(36.56, 548.52)) from 70 cohorts for Prostatectomy. The performance targets were 500 mL, 490 mL and 500mL for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- Cystectomy saw 17 literature-based cohorts report transfusion rates with an SLR rate of 12.85% (95% PI:(1.01%, 68.01%)), 4.75% (95% PI:(0.78%, 23.96%)) from 49 cohorts for Nephrectomy, and Prostatectomy saw a SLR rate of 1.77% (95% PI:(0.05%, 39.12%)) from 76 cohorts. The performance targets were 55.0%, 30.0%, and 60.0% for Cystectomy, Nephrectomy and Prostatectomy, respectively.

- Rates of device related conversion were not reported within literature. The performance targets were 15.0% for each of Cystectomy, Nephrectomy and Prostatectomy.
- The SLR average hospital length of stay was 11.30 days (95% PI:(3.02, 26.98)) from 16 cohorts for Cystectomy, 4.12 days (95% PI:(0.22, 24.41)) from Nephrectomy (36 cohorts), and within Prostatectomy there were 52 cohorts with an average rate of 4.94 days (95% PI:(0.71, 14.19)). The performance targets were 7 days, 7 days, and 11 days for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- Readmission rates (through 30 days) were not commonly reported in literature with 3, 3, and 7 literature cohorts reporting it for Cystectomy, Nephrectomy and Prostatectomy, respectively. Rates were 21.73% (95% PI:(4.57%, 61.67%)) for Cystectomy, 6.35% (95% PI:(1.39%, 24.62%)) for Nephrectomy, and 5.00% (95% PI:(0.95% 22.39%)) for Prostatectomy. The performance targets were 39.4%, 16.8%, and 30.0% for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- Reoperation rates (through 30 days) were also not commonly reported with 4 cohorts for Cystectomy, none for Nephrectomy, and 3 for Prostatectomy. The SLR rate for Cystectomy was 7.25% (95% PI:(0.34%, 63.86%)), and 1.14% (95% PI:(0.03%, 28.37%)) for Prostatectomy. The performance target was 25.6% for each of: Cystectomy, Nephrectomy and Prostatectomy.
- All-cause mortality (through 30 days) was reported in 5 literature cohorts for Cystectomy with an SLR rate of 1.33% (95% PI:(0.65%, 2.71%)), 1.27% (95% PI:(0.00%, 81.52%)) from 4 cohorts for Nephrectomy, and 1.51% (95% PI:(0.00%, 99.99%)) from 3 cohorts for Prostatectomy. The performance targets were 35.1%, 24.3% and 21.0% for Cystectomy, Nephrectomy and Prostatectomy, respectively.
- Rates of device deficiencies were not reported within literature. The performance target was 20.0% for each: Cystectomy, Nephrectomy, and Prostatectomy.

8. Conclusion

Substantial equivalence of the subject device, Hugo RAS System, to the commercially available predicate device, Versius Surgical System, is established in terms of intended use, technological characteristics, and performance testing. The difference in indications for use, for urologic surgical procedures, has been supported with clinical data. The Expand URO IDE clinical study met the performance goals for both the primary safety and primary effectiveness endpoints, and were similar to the SLR comparator. The IDE study reported a device deficiency rate greater than the predicate device reported from post market data collected outside of United States; moreover, the device-related serious adverse event rate was similar to the predicate device and there were no device related deaths. Additionally, device changes have been implemented post-IDE study to improve system performance, which was demonstrated with non-clinical performance testing and clinical performance testing outside of the United States. To further validate the device changes, a post market surveillance study will be conducted in the United States. The comparison of technological characteristics together with the non- clinical and clinical performance data do not raise different questions of safety and effectiveness. Based on this information and compliance to Special Controls for product code SCV, the Hugo RAS System is substantially equivalent to the Versius Surgical System.