

**DE NOVO CLASSIFICATION REQUEST FOR
VERSIUS SURGICAL SYSTEM**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Modular electromechanical surgical system. A modular electromechanical surgical system is a software-controlled electromechanical system with a plurality of individual, fully positionable patient/device interfaces which allows a qualified user to perform surgical techniques during minimally invasive surgical procedures.

NEW REGULATION NUMBER: 21 CFR 878.4964

CLASSIFICATION: Class II

PRODUCT CODE: SCV

BACKGROUND

DEVICE NAME: Versius Surgical System

SUBMISSION NUMBER: DEN230078

DATE DE NOVO RECEIVED: November 21, 2023

SPONSOR INFORMATION:

CMR Surgical Limited
% Daniel & Daniel Consulting
340 Jones Lane
Gardnerville, Nevada 89460

INDICATIONS FOR USE

The Versius Surgical System is indicated as follows:

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, electro-surgery, and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electro-surgery 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.

LIMITATIONS

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

Use of the Versius Surgical System must be administered under the direct supervision of a qualified and trained physician, after appropriate evaluation.

The long-term safety and effectiveness of the device for use with or treatment of cancer has not been established.

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

DEVICE DESCRIPTION

The Versius Surgical System is intended to assist in the accurate control of its surgical endoscopic instruments across a range of surgical procedures.

The system comprises (Figure 1):

- a surgeon console,
- a visualization bedside unit
- up to three instrument bedside units
- surgical attachments comprising an endoscopic camera and surgical instruments,
- and sterile drapes

Each bedside unit includes a robot arm to which the endoscopic camera and instruments are attached.

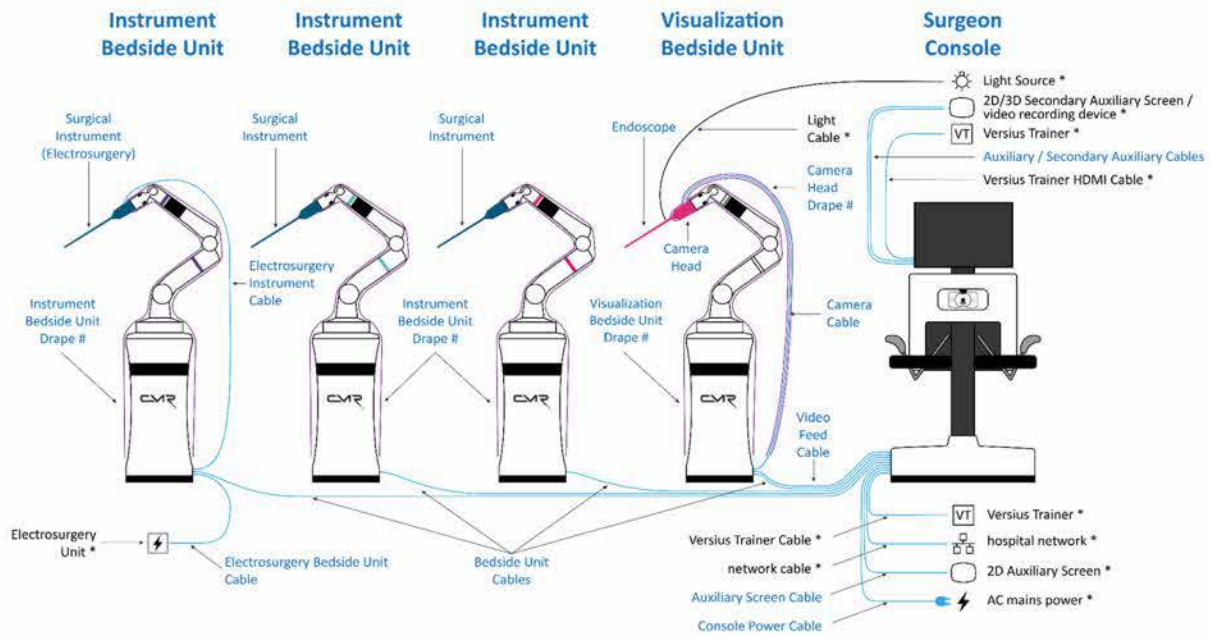


Figure 1. The Versius Surgical System

The Bedside Units have been designed to be separately movable so that they can be set up and moved around the Surgical Bed. During a surgical procedure (Figure 2), the Bedside Units are placed in fixed positions around the Surgical Bed to suit the Surgical Port placement and access appropriate for the procedure at hand.

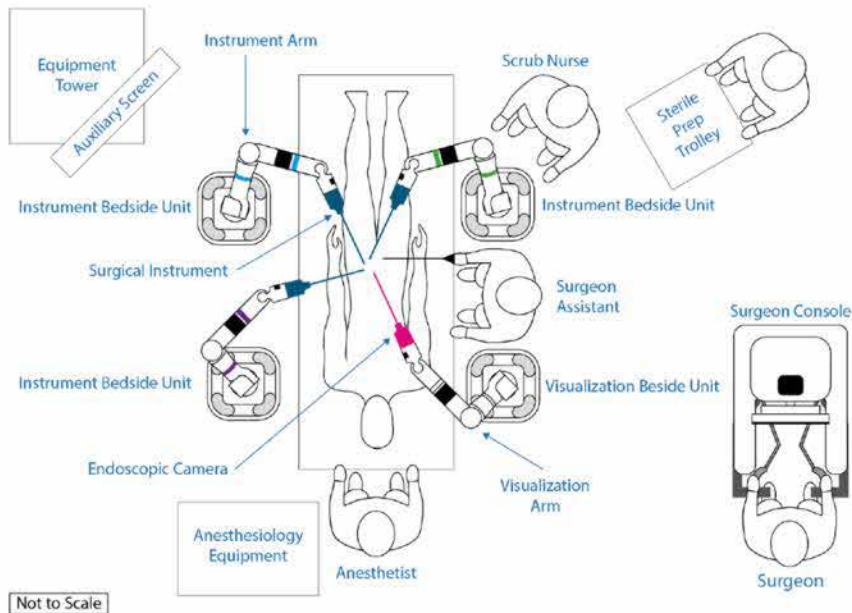


Figure 2. Overhead view of a possible system layout in the OR.

Surgeon Console

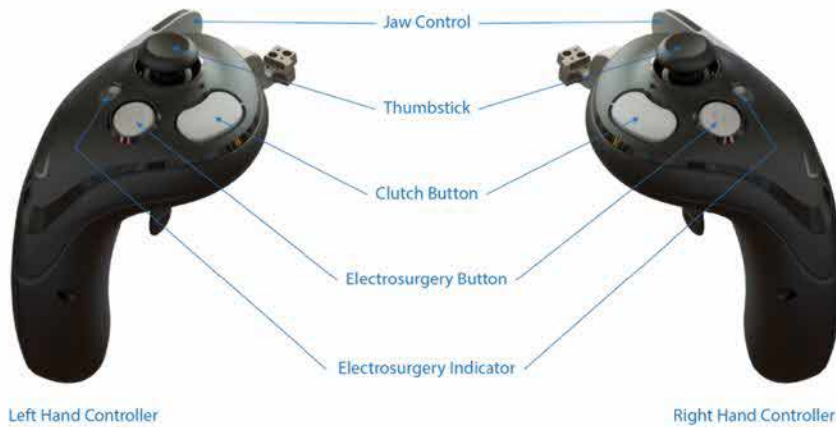
The surgeon interacts with the system via the surgeon console (Figure 3) using hand controllers (Figure 4) and an interactive head-up display (HUD). The HUD provides a three-dimensional video from the endoscopic camera together with a display overlay. The height of the surgeon console is adjustable, which allows the surgeon to sit or stand during surgery.

The Surgeon Console (Figure 3) is the main interface for the Surgeon using the System. It connects to the AC mains power supply and acts as a power and data communications hub to support all connected bedside units. The height of the display screen and the height of the arm rest are independently adjustable, allowing the surgeon to choose whether to stand or sit while using the Surgeon Console.



Figure 3. The Surgeon Console

The surgeon console, which is positioned outside of the sterile field, is used by the surgeon to control the movements and use of the robot arms and thus the endoscope and instruments, using two hand controllers (Figure 4).



Left Hand Controller
 Figure 4. The Hand Controllers

Right Hand Controller

The surgeon views the live display on a high-resolution surgeon console screen, comprising a three-dimensional (3D) endoscopic image of the patient anatomy and a HUD that displays instrumentation icons and other user interface features. A graphical representation of the HUD overlay is shown in Figure 5 below.

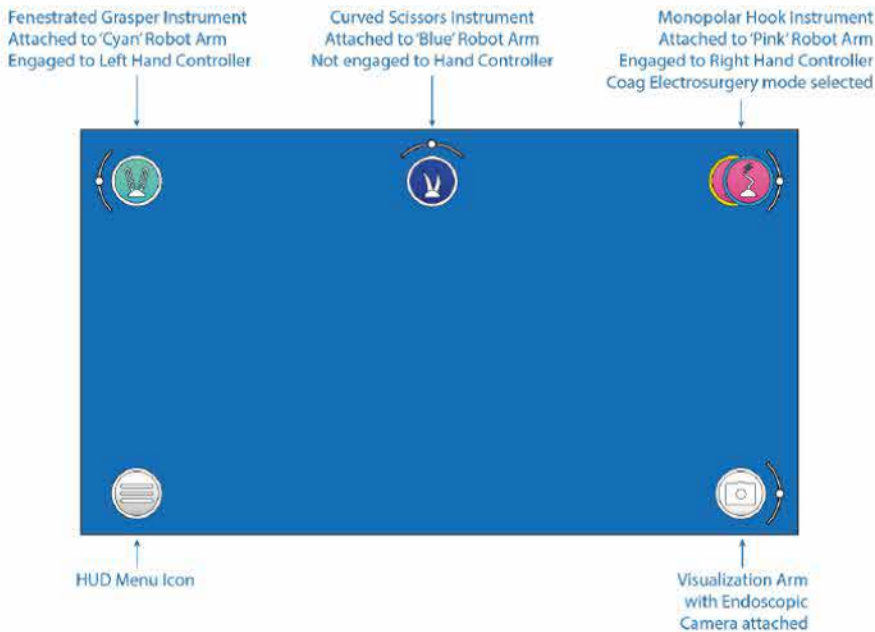


Figure 5. Representation of the HUD Overlay

The surgeon can record the video of the surgical procedure on a user-supplied SD card. The console also records system telemetry data that can be used post-procedure for use in diagnostics and post-market activities. When the surgeon console is connected to a local network, this telemetry data is uploaded to the Versius Cloud service.

Bedside Units

A bedside unit comprises a surgical cart and a robot arm (Figure 6). Surgical instruments and an endoscopic camera are attached to the distal ends of the instrument arms and the visualization arm respectively. The surgical instruments can perform various surgical tasks under the control of the surgeon and in response to input from the two hand controllers.

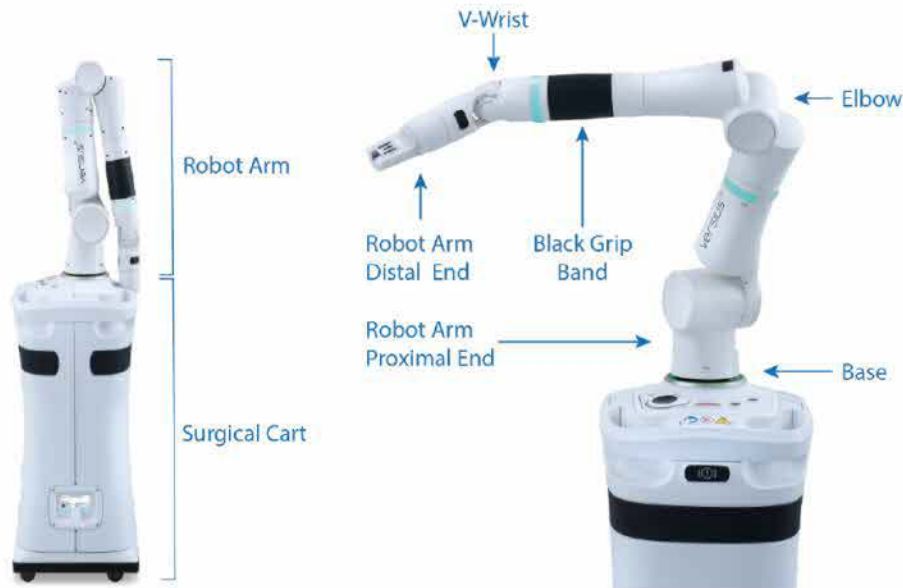


Figure 6. The Bedside Unit

The bedside units are positioned individually around the surgical bed. They obtain power from the surgeon console via a bedside unit cable and can be connected in various configurations to suit the OR layout.

The behavior of the robot arms is determined by user-selected arm modes. In ‘Surgical Mode,’ the robot arms move under the control of the surgeon. There are also several ‘Compliant’ arm modes in which the arms can be manipulated by the bedside team. Other arm modes include ‘Sleep Mode’ where the robot arm adopts the folded pose and ‘Locked Mode.’ Bedside units include a brake mechanism that immobilizes the surgical cart when in use.

An instrument arm comprises 11 moving Joints (J1 – J11), where J1-8 are used to move/position the robot arm and J9-11 are used to manipulate the attached instrument’s end effector (Figure 7). A visualization arm comprises J1-8 and an attachment mechanism at its distal end for the endoscopic camera.

(b)(4)

Figure 7. Kinematic diagram of the robot arm (J1 - J8) and the surgical instrument (J9-J11)

Versius Surgical Instruments

The Versius Surgical Instruments (Figure 8) comprise non-electrosurgery instruments and electrosurgery instruments.

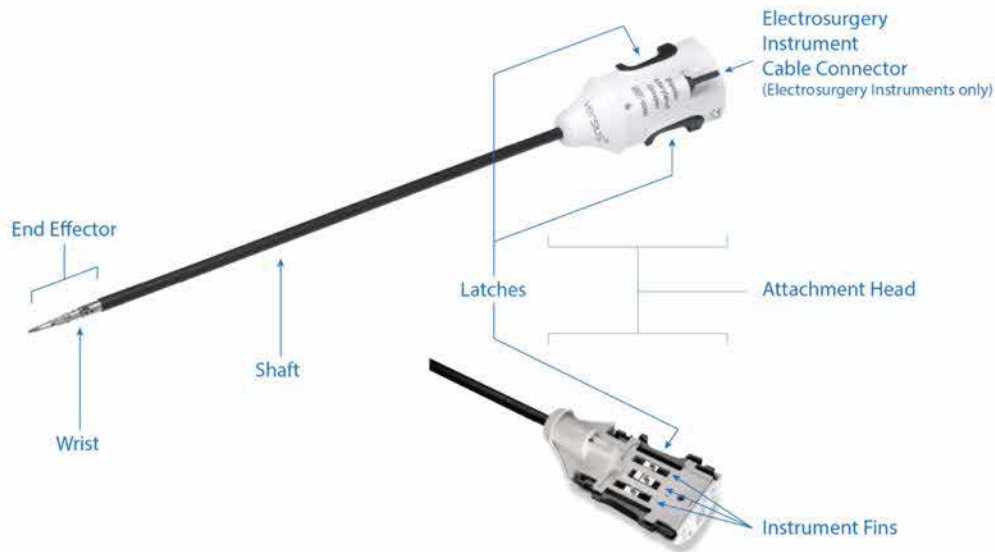


Figure 8. Versius Surgical Instrument

The surgical instruments available for use with the Versius Surgical System are shown in Figures 9 and 10. They are reusable and supplied pre-programmed with a maximum number of uses.

Fenestrated Grasper



Curved Scissors



Needle Holder



Figure 9. Non-electrosurgical Instruments

Monopolar Hook



Bipolar Maryland Grasper



Figure 10. Electrosurgical Instruments

Versius Surgical Instruments attach to the distal end of the instrument arm via a latching mechanism located on the underside of the instrument's attachment head. The mechanical forces used to articulate the instrument's end effector are transferred from the instrument arm's joints to 'instrument fins' located on the underside of the attachment head. Electrosurgery instruments are supplied with electrosurgery energy via the electrosurgery instrument cable.

Endoscopic Camera

The Versius Endoscopic Camera (Figure 11) comprises an endoscope and a camera head. The endoscopic camera attaches to the visualization arm via a latch mechanism on the bottom face of the camera head.



Figure 11. The Endoscopic Camera

The endoscope is supplied in two variants: 30 Degree and 0 Degree. The endoscope is supplied with an illumination light source via a detachable light cable. The camera head includes an integral camera cable that carries the endoscopic video feed and endoscopic camera control signals.

Sterile Drapes

The drapes are sterile, single-use items manufactured by an approved third-party. There are three types of custom sterile drapes/drape sets:

- Instrument bedside unit drape set
- Visualization bedside unit drape set
- Camera head drape

The instrument arm drape includes a replaceable sterile drape cap insert that maintains the sterile barrier between instrument arm and the attached surgical instrument.

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 Versius 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 Versius.

TABLE 1. BIOCOMPATIBILITY/MATERIALS

Test	Method	Results
Cytotoxicity	MEM Elution - ISO 10993-5	PASS
Sensitization	ISO 10993-10 – Guinea Pig Sensitization Assays	PASS
Irritation	ISO 10993-21 - Intracutaneous Injections Test	PASS
Acute Systemic Injection	ISO 10993-11 - Systemic Injection Test	PASS
Material-mediated Pyrogenicity	ISO 10993-11 – Rabbit Pyrogen Test	PASS
Hemocompatibility	ISO 10993-4, ASTM F756 - Hemocompatibility	PASS

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

TABLE 2. SHELF LIFE/STERILITY

Test	Method	Results
Versius Console, Bedside Units and Accessories		
Cleaning	AAMI TIR30, AAMI TIR12, FDA Reprocessing Guidance (2015/A2017)	PASS
Disinfection	AAMI TIR1, 2 ISO 15883-1	PASS
Versius Surgical Instruments		
Cleaning (simulated use)	AAMI TIR12, AAMI TIR30, ISO 17664-1, ISO 17665, ISO 15883-5, AAMI ST98	PASS
Cleaning	AAMI TIR12, AAMI TIR30, ISO 17664-1, ISO 15883-5, AAMI ST98	PASS
Disinfection	ISO 15883-5, ISO 15883-1, AAMI ST79	PASS
Sterilization	ISO 17665-1, EN 556-1, AAMI TIR12, AAMI ST79, ANSI/AAMI/ISO 17665-1:2006 (R2013)	PASS
Endoscopes		
Cleaning (simulated use)	AAMI TIR12, AAMI TIR30, ISO 17664, ISO 15883-5, AAMI ST98	PASS
Cleaning	AAMI TIR12, AAMI TIR30, ISO 17664, ISO 15883-5, AAMI ST98	PASS
Disinfection	ISO 15883-5, ISO 15883-1, AAMI TIR12	PASS
Sterilization	ISO 17665-1, AAMI ST79, EN 556-1, AAMI TIR12, ANSI/AAMI/ISO 17665-1:2006 (R2013)	PASS
Electrosurgery Cables		
Cleaning	AAMI TIR12, AAMI TIR30, ISO 17664, ISO 15883-5, AAMI ST98	PASS
Disinfection	ISO 15883-5, ISO 15883-1, AAMI TIR12	PASS
Sterilization	ISO 17665-1, AAMI ST79, EN 556-1, AAMI TIR12, ANSI/AAMI/ISO 17665-1:2006 (R2013)	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	ASTM D4169 (2022), ISTA 7D, ASTM D6179-20, ASTM D880-86, ASTM D4728-17 (2022), ASTM D6653/D6653M-13 (2021), D4728-17 (2022), ASTM D6344-04	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.

TABLE 4. ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

Test	Method	Results
Electrical Safety, Alarms & Usability	IEC 60601-1:2005, AMD1:2012 (+ USA national differences) IEC 60601-1-6:2010 + A1:2013, (Usability/Human Factors) ANSI/AAMI/IEC 60601-1-8:2006 + A1:2012, (Alarms) IEC 60601-2-18:2009, (endoscopic equipment) ANSI/AAMI/IEC 80601-2-77:2020, (RASE) ANSI/AAMI/IEC 60601-2-2:2017, (HF surgical equipment)	PASS
EMC (Immunity)	IEC 60601-1-2:2014 + A1:2020 IEC / EN 61000-4-39 Radiated Fields in Close Proximity Immunity Test	PASS
EMC (Emissions)	IEC 60601-1-2:2014 CISPR 11:2015/AMD1:2016	PASS
Wireless co-existence	AAMI TIR69:2017 ANSI C63.27:2017 AIM 7351731	PASS

MAGNETIC RESONANCE (MR) COMPATIBILITY

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

SOFTWARE & CYBERSECURITY

A failure or latent flaw in the software of the Versius 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.

The device has been determined to be a cyber device as determined by section 524B of the FD&C act. Cybersecurity documentation was provided in accordance with the September 27, 2023 FDA guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”. The documentation provided demonstrated a reasonable assurance the device is cybersecure.

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 modular design of the Versius (e.g., tipping, tripping, and bumping).

The bench tests characterize device performance and design verification for the Versius 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
Bedside Unit stability and movement	Demonstrate the stability of the Surgical Cart after applying external forces and the ability of the Cart to be moved by a User	PASS
Bedside Unit brake & height adjustment	Verify that the System prevents an Operator from releasing the Surgical Cart Brake or adjusting the Robot Arm height during surgery	PASS
Electromechanical arm motion accuracy	Demonstrate that the Versius Surgical System arms can reach the entire intended workspace based on pre-defined acceptance criteria.	PASS
Instrument motion accuracy	Demonstrate the accuracy of the surgical instruments and quantify the amount of unintended motion when under surgeon control.	PASS
System Latency	Determine system latency of each tested degree of freedom to ensure that it is within the pre-defined acceptable range.	PASS

Droop	Demonstrate under single fault conditions that the end-effector of the Versius Surgical System does not droop or apply force under gravity based on the pre-defined acceptance criteria.	PASS
System component integrity, loading and mechanical properties	Demonstrate the component's rigidity, yield strength, ability to withstand anticipated loads, tensile forces and torque application and evaluate the lift and pull force of the robotic arm.	PASS
System interfaces	Demonstrate that the system's components, when used together, are compatible and operate as expected.	PASS
Electrical properties	Verify system grounding, insulation, ingress protection, power controls	PASS
Electrosurgical compatibility	Active electrode (monopolar and bipolar) performance testing	PASS
Arm simulated use testing	Demonstrate that the Versius Surgical Arms maintain functionality for a full, worst-case surgical procedure.	PASS
Thermal effects on tissue	Evaluate the thermal effects on tissue caused by the electrosurgical functionalities (monopolar coagulation and bipolar coagulation) of the Versius Electrosurgical Instruments	PASS

ANIMAL TESTING

An animal study was conducted in compliance with GLP requirements using the Final Finished Device version of the Versius Surgical System. Three acute animals and three chronic animals each underwent a complete robotic cholecystectomy procedure. An additional six animals (three chronic and three acute) received total laparoscopic hysterectomy procedures (this procedure was used to support the general suturing indication of the device). The objective of the study was to validate that the Versius Surgical System and instruments are safe and effective through the completion of cholecystectomy via evaluation in both an acute non-recovery porcine models, and a chronic recovery porcine model recovered to 28 ± 3 days post-operative. Specifically, the intent was to demonstrate that the System could be used for accurate and instinctive manipulation of tissue such as grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery and suturing. Endpoints included overall animal health, test article performance, and local tissue response. All endpoints were evaluated per protocol for this study, there were no adverse effects or unexpected tissue effects, and the Versius system performed all functions as indicated.

TRAINING

The sponsor has developed a Versius-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. Versius 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 Versius 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 cadaveric surgical procedure in a representative simulated operating room. Each team received representative in-person training from CMR’s professional education team, totaling three days for the surgeon and two days for the remainder of the surgical team. All participants (sixteen teams) were able to complete the required tasks within the study in a way that demonstrates that no pattern of use error or difficulties was present. Included in the validation study were critical tasks and hazards related to the modular nature of the bedside units, including but not limited to cable tripping, knocking of robotic arm, robotic arm collisions, and tipping/inadvertent movement of the bedside unit. The study validated that the final design of the Versius Surgical System met the needs of the intended users and that all foreseeable use-related risks had been mitigated as much as possible.

SUMMARY OF CLINICAL INFORMATION

Cholecystectomy

The clinical testing included two studies to assess the safety and effectiveness of the Versius Surgical System in robot assisted laparoscopic Cholecystectomy; one was conducted in Poland and the other in India.

The Poland study was a prospective, single-center, three-surgeon, single-arm, 30 subject study. The principal investigator performed 8 cases in the study, while two other surgeons performed 14 and 8 cases respectively. All surgeons were generalists. The principal investigator had fifteen years of open surgery experience with no previous robotic surgery experience. The other two surgeons had approximately ten years of laparoscopic surgery experience with no previous robotic surgery experience.

The India study was a prospective, single-center, single-surgeon, single-arm, 30 subject study. The surgeon was a generalist with over 35 years of open and laparoscopic surgery. Prior to the clinical study, he completed over five hundred cholecystectomy cases using the OUS commercially available version of the Versius Surgical System.

General Inclusion

Subjects in each study were required to meet the following criteria for entrance to the study:

- Patient deemed suitable for laparoscopic Cholecystectomy procedure using Versius Surgical System by the Principal Investigator Surgeon
- Patients able to provide written informed consent to participate in the study

- Male and Female, aged 18 years or above
- Female of childbearing potential must not be pregnant and agree to not become pregnant for the duration of the study
- Patients with BMI <40. Priority BMI 25 to 40

General Exclusion

Subjects were to be excluded from participating in this trial if they met any of the following exclusion criteria prior to initiation of the surgical procedure:

- Patient participation in an investigational clinical study within 30 days before screening
- Inability or difficulties to provide informed consent
- Uncontrolled hypertension (= \geq Systolic: 180 mmHg/Diastolic: 120 mmHg)
- Diabetes mellitus (Glycemia > 11mmol/L; >200 mg/dL)
- Oncological cases, patients undergoing surgery or treatment for malignant disease
- Patients who fall into American Society of Anesthesiologist's (ASA) Class IV or above
- History of chronic alcohol or drug abuse
- Chronic renal failure or on dialysis
- Significant medical history or immunocompromised
- Subjects with any other clinically significant unstable medical disorder, life threatening disease, or anything else in the opinion of the Investigator which would contra-indicate a surgical procedure
- Patient tested COVID positive within last 30 days of screening
- Patient tested COVID positive within 48 hours day the of the procedure

Study Endpoints

Primary Effectiveness Endpoints

The primary efficacy endpoint was quantified as the rate of unplanned conversion to other minimal access surgery (MAS) or open surgery (OP).

Primary Safety Endpoints

The primary safety endpoint was measured by rate of total intraoperative and postoperative serious adverse event (SAE) up to 30 days post procedure.

Secondary Endpoints

Secondary objectives included:

1. Operative time – From incision to skin closure
2. Estimated blood loss (intra-operative)
3. Blood transfusion (intra-operative)
4. Intra-operative complications
5. Return to operating room within 24 hours
6. Length of hospital stay

7. Readmission to hospital within 30 days
8. Reoperation within 30 days
9. Mortality rate at 30 days
10. Histopathology of surgically removed specimen
11. Device deficiencies and use errors regardless of relationship to an adverse event
12. All Adverse Events
13. Device performance data including unplanned instrument usage, clashes, collision detection, alarms

Results

Table 6 compares US patient and study subject demographics.

TABLE 6. DEMOGRAPHIC COMPARISON

	US Data Sources¹	India	Poland
Sample Size	298,188 319,184	30	30
Female, n (%)	70%	53%	70%
Age in years, Mean (range)	49.4 ± 17.5 and 44 ± 12	42.7 (22-69)	56.1 (24-79)
BMI in kg/m², mean (range)	30 (IQR 26-35)	26.6 (18-34.1)	27.2 (19.6-38.9)
Indications for Procedure	Cholecystitis (chronic or acute) was the indication for surgery in >80% of patients.	Largest % Symptomatic Cholecysto- lithiasis	Largest % Symptomatic Cholecysto- lithiasis
Concomitant comorbidity, n (%)	hypertension in roughly 40% of patients, followed by diabetes in the 10% range as well as smoking and obesity rates around 20%.	13 (43%)	26 (87%)

¹US Data Sources

New York State's State Planning and Research Cooperative System (SPARCS), 20091-2017
Truven Marketscan Research Database, 2011-2015

Subject BMI for the studies was lower than the US mean BMI, and racial data were not available for a detailed comparison of comorbidities.

Poland study

A total of 30 patients signed an informed consent form in this study and were found eligible for the study. All 30 patients completed the surgery, were discharged from hospital and completed

the 30-day clinical follow up, until end of study. No early discontinuations or withdrawals were recorded in this trial.

Thirty patients underwent robotically assisted cholecystectomy. Patients had a mean age of 56.1 years (range 24-79), mean BMI of 27.2 kg/m² (range 19.6-38.9) and 21(70 %) were females.

26 patients (87%) had at least one comorbidity, while 13 (43%) had a history of abdominal / pelvic surgery. 2 patients (7%) had an American Society of Anesthesiologists (ASA) Status of I, 21 (70%) had an ASA status of II, and 7 (23%) had an ASA status of III.

19 (63%) of the patients were operated on due to Calculus of gallbladder without cholecystitis while the other 11 (37%) were operated for other related reasons.

Effectiveness was measured by the rate of successful completion of the procedure without unplanned conversion to other surgical techniques. Twenty-nine (29) (96.6%) procedures were completed with Versius Surgical System as planned, while in one case the surgeons converted to open surgery, due to challenging anatomy that did not allow safe minimal invasive surgery, according to the principal investigator (PI).

Safety was assessed by the rate of SAEs. Clinical follow up was 30 days on average (Range 28-32 days). A total of 3 (10%) adverse events were reported in the trial, 2 (6.6%) of which were serious, both postoperative and reported in the same patient. Those two SAEs were classified as Moderate, Clavien Dindo grade III, and both not related to Versius Surgical System. Both SAEs occurred in the patient that underwent open surgery following a conversion. There were no SAEs reported in any of the cases that were performed with Versius Surgical System.

TABLE 7. SERIOUS ADVERSE EVENTS (POLAND)

Follow up (days), mean (range)	30 (28 -32)
Total intra-operative adverse events n, (%)	1, (3.3%)
Intra-operative serious adverse events n, (%)	0, (0%)
Total post-operative adverse events n, (%)	2, (6.6%)
Post-operative serious adverse events n, (%)	2, (6.6%)

TABLE 8. EFFICACY AND SECONDARY OUTCOMES (POLAND)

Total unplanned conversions, n (%)	1, (3.3%)
Unplanned conversion to open surgery	1, (3.3%)
Unplanned conversion to Laparoscopic surgery	0, (0%)
Mean Operative time (mins), (Range)	90 [50 – 300]
Hospital stay (days), median(range)	1 (1-32)
Blood loss (ml) n, (%)	
<100	30, (100%)
≥100	0, (0%)
Blood transfusion n, (%)	0, (0%)
Device Deficiency /Use Error during surgery n, (%)	4, (13%)
Reoperation within 24 hours n, (%)	0, (0%)
Readmission to hospital within 30 days n, (%)	0, (0%)

Survival n,(%)	30 (100%)
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India Study

A total of 32 patients signed an informed consent in this study, from which two were found not to meet the inclusion/exclusion criteria and hence excluded before participating in any of the study activities. The remaining 30 patients completed the procedure as planned, were discharged from hospital and completed the 30-day clinical follow-up until end of study.

Thirty patients underwent robotically assisted cholecystectomy. Patients had mean age of 42.7 years (Range 22-69), mean BMI of 26.6 Kg/m² (Range 18.07-34.16) and 16 (53%) of the patients were females.

Thirteen (43%) patients had at least one comorbidity, while 6 (20%) had a history of abdominal/pelvic surgery. Eighteen (18) (60%) patients had American Society of Anaesthesiologists (ASA) Status of 1, while the remaining 12 had ASA status of 2.

Indications for surgical intervention for cholelithiasis were: 9 with acute cholecystitis, 9 without cholecystitis, 6 due to symptomatic gall stone disease, 3 for Chronic cholecystitis, 1 case due to Calculus of gallbladder without cholecystitis with obstruction, 1 for acute on chronic cholecystitis, and 1 due to chronic calculus cholecystitis.

The primary procedure for all 30 patients was total cholecystectomy, with no performed secondary procedure on the day of surgery.

Effectiveness was measured by the rate of successful completion of the procedure without unplanned conversion to other surgical techniques. No conversions were reported in this trial, and all 30 (100%) procedures were completed with Versius Surgical System as planned.

Safety was assessed by the rate of serious adverse events. Clinical follow up was 30 days on average (Range 29-31). No intraoperative or postoperative adverse or serious adverse events were reported up to 30 days after the procedure.

TABLE 9. SERIOUS ADVERSE EVENTS (INDIA)

Follow up (days), mean (range)	30 (29-31)
Mean hospital stay (days), Range	1 (1-2)
Intra-operative adverse events n, (%)	0, (0%)
Intra-operative serious adverse events n, (%)	0, (0%)
Post-operative adverse events n, (%)	0, (0%)
Post-operative serious adverse events n, (%)	0, (0%)
Reoperation within 24 hours n, (%)	0, (0%)

TABLE 10. EFFICACY AND SECONDARY OUTCOMES (INDIA)

Mean Operative time (mins), Range	70 (44-133)
Blood loss (ml) n, (%)	
<100	30, (100%)

≥100	0, (0%)
Blood transfusion n, (%)	0, (0%)
Conversion to open	0, (0%)
Conversion to Lap	0, (0%)
Device Deficiency during surgery n, (%)	1, (3%)
Reoperation within 24 hours n, (%)	0, (0%)

Table 11 details the major procedural endpoints by surgeon for both cholecystectomy studies.

TABLE 11. MAJOR PROCEDURAL ENDPOINTS BY SURGEON

Surgeon background	Surgeon 1	Surgeon 2	Surgeon 3	Surgeon 4
Location	India	Poland	Poland	Poland
Main practice	Lap and Robotic	Open (robotic naive)	Lap (robotic naive)	Lap (robotic naive)
Surgeon type	General	General	General	General
Years of experience	35	15	~10	~10
Outcome				
Sample size	n=30	n=8	n=8	n=14
Mean Op time (mins), Range	70 (44-133)	125 (80-300)	82 (55-120)	74 (50-100)
Conversion to open	0, (0%)	1, (12.5%)	0, (0%)	0, (0%)
Conversion to Lap	0, (0%)	0, (0%)	0, (0%)	0, (0%)
Blood loss (ml)n, (%)				
< 100ml	30, (100%)	8, (100%)	8, (100%)	14, (100%)
≥ 100ml	0, (0%)	0, (0%)	0, (0%)	0, (0%)
Blood transfusion n, (%)	0, (0%)	0, (0%)	0, (0%)	0, (0%)
Intra-operative adverse events n, (%)	0, (0%)	0, (0%)	1, (12.5%)	0, (0%)
Intra-operative serious adverse events n, (%)	0, (0%)	0, (0%)	0, (0%)	0, (0%)
Reoperation within 24 hours n, (%)	0, (0%)	0, (0%)	0, (0%)	0, (0%)
Median hospital stay (days), Range	1 (1-2)	1 (1-32)	1(1-2)	1(1-2)
Post-operative adverse events n, (%)	0, (0%)	0, (0%)	0, (0%)	0, (0%)
Post-operative serious adverse events n, (%)	0, (0%)	2, (25%)	0, (0%)	0, (0%)
30-day readmission	0, (0%)	0, (0%)	0, (0%)	0, (0%)
30-day reop	0, (0%)	0, (0%)	0, (0%)	0, (0%)
Time to complete training on port placement and instrument adjustment, (mins), Median (IQR)	1.8 (10.2)	4 (11.2)	3.6 (7.6)	5.7 (5.7)

Suturing-Related Study Results

In addition to the cholecystectomy data, both the Poland and India studies presented data to support the general use of the needle holder for suturing. The data were from 60 prospective clinical trial total laparoscopic hysterectomy (TLH) cases (30 each from Poland and India). Only the Versius System Needle holders were used for driving the needle in all cases. Effectiveness was demonstrated by 42-day follow-up with 0 out of 60 occurrences of vaginal vault dehiscence.

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 detection 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) A statement that the device has not been evaluated for the treatment of cancer or any specific disease or condition.
- (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 a modular electromechanical surgical system.

TABLE 12. RISKS TO HEALTH

Risks to Health	Mitigation Measures
Electrical fault, electromagnetic interference, mechanical fault, or system malfunction resulting in:	Clinical performance testing Postmarket surveillance Animal performance testing

Risks to Health	Mitigation Measures
<ul style="list-style-type: none"> • Tissue injury • Electric shock • Prolonged procedure time. 	Non-clinical performance testing Annual reporting Electrical safety testing Electromagnetic compatibility testing Software verification, validation and hazard analysis Labeling
Use error leading to patient harm or prolonged procedure time: <ul style="list-style-type: none"> • Re-operation • Hematoma • Tissue injury • Increased blood loss 	Clinical performance testing Postmarket surveillance Animal performance testing Training Annual reporting Human factors testing Labeling
Infection	Clinical performance testing Postmarket surveillance Animal 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, the modular electromechanical surgical system 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 (i.e., rate and number of conversions to open or other minimally invasive surgery, rate of device related adverse events and their severity, cause, and outcomes) must be reported with relevant descriptive or developmental performance measures.

- (2) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must evaluate:
 - (i) All surgical tasks pertinent to the device's intended use, demonstrating the device can accurately and precisely control attached surgical instruments without excess of adverse events, device and not-device related.
 - (ii) Acute and chronic histopathology and gross examination of the affected organs and surrounding tissue.
- (3) 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.
- (4) 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.
- (5) 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 issues related to the modular nature of the patient/device interfaces.
- (6) 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 of the device has not been evaluated for outcomes related to the treatment or prevention of cancer, including but not limited to risk reduction, overall survival, disease-free survival and local recurrence, 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.
- (7) 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.
- (8) Software verification, validation, and hazard analysis must be performed.
 - (9) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.
 - (10) Performance data must demonstrate the sterility of all patient-contacting device components.
 - (11) 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.
 - (12) Performance data must validate the reprocessing instructions for the reusable components of the device.
 - (13) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.
 - (14) Performance data must demonstrate that all patient-contacting components of the device are non-pyrogenic.
 - (15) 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 and animal studies 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 Versius Surgical System have been identified, including:

1. Use Errors Related Risk Resulting in Patient Injury
 - a. Injury to surrounding tissues – i.e., abdominal wall, intra-abdominal organs, or blood vessels
 - i. Pressure/obstruction of blood vessels
 - ii. Injury to surrounding tissue due to movement of the device
 - iii. Damage to tissue surrounding the gel-port
 - b. Postoperative hemorrhage
 - c. Conversion to open surgery
2. Increased physician learning curve because the hand controllers do not mimic standard laparoscopic instrument interfaces
3. Collision, tripping, and stability hazards due to the modular design of the bedside stations
4. Electrical, Mechanical, or System Malfunction Risk Resulting in Patient Injury

5. Thermal damage to surrounding tissue
6. Adverse tissue reaction
7. Infection

The probable benefits of the device are also based on nonclinical laboratory and animal studies as well as data collected in the clinical studies as described above.

Minimal access cholecystectomy in general is considered to be a relatively safe procedure with low rates of intra and postoperative complications. Use of the Versius device will provide an alternative method, compared to currently available options, for patients to safely and effectively undergo cholecystectomy procedures, thus functioning as a tool that may be used to treat a variety of biliary conditions including but not limited to acute cholecystitis, gallstone pancreatitis and chronic cholecystitis/biliary colic. This device will help facilitate minimally invasive surgery for patients who do not have access to current robotic and minimally invasive technologies. Well-established benefits of minimally invasive procedures have been identified when compared to open procedures, including low surgical site occurrence/infection rates, low blood loss leading to reduced blood transfusion rates, and low hospital length of stay. In addition, the Versius Surgical System has smaller diameter instruments (5 mm) compared to other cleared mainstream robotic devices in the US (8 mm), thus allowing for smaller trocar incisions. Versius also has benefits in ergonomics and dexterity compared to traditional laparoscopic procedures. Versius can increase dexterity by eliminating the motion reversal associated with these procedures. Versius also allows for motion scaling allowing for more consistent and precise manipulation. Versius also allows the surgeon to sit or stand according to their preference during the procedure, leading to less surgeon fatigue. The modular design and small footprint of the Versius allows it to be used in smaller Operating Rooms compared to mainstream robotic systems in the US. This modular nature also allows the operating staff to only bring in the number of bedside units needed for the procedure and also to swap out a bedside unit if needed. The Versius system is designed to be used in an OR and to be quickly and easily moved from room to room. These additional features of the Versius Surgical System are designed to lead to greater patient access and increased use of minimally invasive techniques. It offers another option compared to open, traditional laparoscopic or traditional robotic where the devices are extremely large and costly.

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 Versius Surgical System has both benefits and risks for the following indication statement:

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, electro-surgery 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.

Use of the Versius device will provide an alternative method for patients to undergo cholecystectomy 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 Versius Surgical System operates using similar principles as other robotically assisted surgical devices, but it has modular bedside units compared to the monolithic existing cleared, approved, or granted devices. Additionally, the surgical steps and techniques used for cholecystectomy are identical to other robotic and laparoscopic approaches and therefore carry the same level of risk as traditional cholecystectomy 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. The modular bedside units can introduce unique hazards related to stability, collision, and tripping. 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 either of the two 30-subject studies conducted with the device in Poland and India. The device has shown high efficacy in the studies (96.6% Poland, 100% India) 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 Versius system. Each study enrolled only 30 subjects, had a small number of surgeons, 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 four surgeons (1 in India, 3 in Poland) were included in the studies, and it is not clear if the one robotically experienced surgeon 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 Versius 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 Versius Surgical System is granted and the device is classified as follows:

Product Code: SCV

Device Type: Modular electromechanical surgical system

Regulation Number: 21 CFR 878.4964

Class: II