December 16, 2025

CMR Surgical Limited
% Michael Daniel
President
Daniel & Daniel Consulting
PO Box 129
Minden, Nevada 89423

Re: K252111
Trade/Device Name: Versius Surgical System (Versius Plus)
Regulation Number: 21 CFR 878.4964
Regulation Name: Modular Electromechanical Surgical System
Regulatory Class: Class II
Product Code: SCV
Dated: November 17, 2025
Received: November 17, 2025

Dear Michael Daniel:

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

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

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

Your device is also subject to, among other requirements, the Quality 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).

Sincerely,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2025.12.16 08:02:10 -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.

Submission Number *(if known)*

K252111

Device Name

Versius Surgical System (Versius Plus)

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

I. SUBMITTER INFORMATION

Submitter: CMR Surgical
1 Evolution Business Park
Milton Road
Impington
Cambridge CB24 9NG
United Kingdom

Contact: Rob Lally
QARA Executive
Phone number: +1 904 960 4301
Email: rob.lally@cmrsurgical.com

Date Summary Prepared: 27 June 2025

II. SUBJECT DEVICE INFORMATION

Trade Name:	Versius Surgical System
Common Name:	Versius Plus
Classification Name:	Modular electromechanical surgical system
Regulation Number:	21 CFR §878.4964
Regulatory Class:	Class II
Product Code:	SCV
Submission Type:	Traditional 510(k)
Classification Panel:	General & Plastic Surgery

III. PREDICATE DEVICE INFORMATION

Predicate Device:	Versius Surgical System (DEN230078)
Reference Device:	System Green (K212808), manufacturer: Richard Wolf GmbH

IV. DEVICE DESCRIPTION

The Versius® Surgical System is a modular, open console, software controlled, electromechanical system designed for surgeons to perform minimally invasive surgery. It consists of the Surgeon Console, a Bedside Unit with a Visualization Arm (Visualization Bedside Unit), one or more Bedside Unit(s) with an Instrument Arm (Instrument Bedside Unit), detachable Surgical Attachments, System Cables and Sterile Drapes. Surgical Attachments comprise Surgical Instruments, Electrosurgery Instruments and an Endoscopic Camera.

The Surgeon interacts with the System through controls and feedback via the Surgeon Console, which includes the Surgeon Console Screen that displays a composite image of the 3D Endoscope Video Feed and a Display Overlay. The Bedside Team access controls and feedback via the Bedside Units and via an Auxiliary Screen, which displays a 2D or 3D version of the Composite Endoscope Feed.

This 510(k) is for the addition of NIR imaging capability, updated software version, additional Surgical Instruments, and material changes in existing Surgical Instruments.

V. INTENDED USE AND INDICATIONS FOR USE

	Versius Surgical System predicate device (DEN230078)	Versius Surgical System, subject device
Intended Use	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 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.
Indications for Use	The Versius Surgical System is indicated for adult patients 22 years of age and older, eligible for soft tissue minimal access surgery, for cholecystectomy.	The Versius Surgical System is indicated for adult patients 22 years of age and older, eligible for soft tissue minimal access surgery, for cholecystectomy.

VI. TECHNOLOGICAL CHARACTERISTICS

The Versius Surgical System that is the subject device of this 510(k) submission is unchanged from the predicate device in terms of intended use and indications for use. Some technological characteristics have been changed in the subject device compared to the predicate device, which do not raise different questions of safety or effectiveness. The changes in technological characteristics comprise the addition of NIR capability, updated software version, changes in materials in Surgical Instruments, and additional Surgical Instruments, as listed in the table below.

Versius System subsystems	**Versius Surgical System,** **Subject Device comparison with Predicate Device (DEN230078)**
Surgeon Console	A communication port is included for System status and control communications between the Surgeon Console and the NIR (near-infrared) capable light source. Additional video processing for NIR video overlay.
Instrument and Visualization Bedside Units	Latest internal components, identical in form and function.
Software	Latest version of software includes: • Improvements in user interface and robotic control. • Support for updated hardware and new instruments. • Support of new subsystems for communication between the Surgeon console and a NIR-capable light source.

Versius System subsystems	Versius Surgical System, Subject Device comparison with Predicate Device (DEN230078)
System Cables	The light source control cable carries system status and control communications between the surgeon console and the light source when a compatible NIR enabled light source is in use.
Endoscopic Camera and Endoscope	The camera contains 2 image sensors for stereo image capture in the visible spectrum and 2 image sensors for stereo image capture in the near infrared (NIR) spectrum.
Surgical Instruments	Cadiere Grasper; new instrument with shorter jaw design and equivalent grasping function as the predicate device.
	Monopolar Curved Scissors and Sleeve accessory; new instrument to add monopolar electrosurgery function to Curved Scissors, with accompanying insulating sleeve accessory.
	Bipolar Fenestrated Grasper; new instrument with rounded tip jaw design with similar bipolar grasping function as the predicate device.
	Needle Holder (NH), Bipolar Maryland Grasper (BMG), Fenestrated Grasper (FG), Monopolar Hook (MH), Curved Scissors (CS); material changes to support increased number of uses, higher RF voltage and volume manufacturability.

VII. PERFORMANCE DATA

The addition of NIR capability, updated software, changed materials in Surgical Instruments and new Surgical Instruments has been evaluated in terms of the applicable performance and safety requirements for reprocessing, biocompatibility, sterility, packaging, software, cybersecurity, mechanical, electrical and electrosurgical performance, electromagnetic compatibility, electrical safety (60601-1), reliability and human factors for the same indicated procedure (cholecystectomy) as the predicate device. The test methods and acceptance criteria follow the corresponding methods and criteria for the predicate device.

NIR capability testing

The addition of NIR capability to the Versius Surgical System does not change the indications for use or the intended use. Human factors validation has been conducted to confirm the subject device can be used safely and effectively by intended users in the Versius Surgical System's intended environment of use. Additionally, design verification and pre-clinical (porcine model) testing was performed to demonstrate the use of the Versius Surgical System integrated NIR capability, using an equivalent approach to the reference device (Richard Wolf System Green, K212808).

VIII. CONCLUSION

The Versius Surgical System has the same intended use and indications for use as the predicate device, and testing confirms that the subject device performs as well or better than the predicated device, and that the changes in technological characteristics do not raise different questions of safety or effectiveness. Therefore, the modified Versius Surgical System is substantially equivalent to the cleared predicate device.