October 21, 2026

Cmr Surgical Limited
% Michael Daniel
President
Daniel & Daniel Consulting
P.O. Box 129
Minden, Nevada 89423

Re: K261252
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: September 22, 2026
Received: September 22, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MARK TRUMBORE -S Digitally signed by MARK TRUMBORE -S Date: 2026.10.21 15:39:31 -04'00'

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261252

Please provide the device trade name(s).

Versius Surgical System (Versius Plus)

Please provide your Indications for Use below.

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 general surgery for cholecystectomy as well as for gynaecologic surgery for benign total hysterectomy, oophorectomy, salpingectomy, adnexectomy, Ovarian cystectomy, and lysis of Adhesions.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) SUMMARY

I. SUBMITTER INFORMATION

Submitter:	CMR Surgical 1 Evolution Business Park Milton Road Impington Cambridge CB24 9NG United Kingdom
Contact:	Nickie Power Head of Regulatory Affairs Phone number: +44 7711 940120 Email: Nickie.Power@cmrsurgical.com
Date Summary Prepared:	21 October 2026

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 (K252111)

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 being submitted for an expansion of the Indications for Use to include benign gynecologic procedures.

V. 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.

VI. INDICATIONS FOR USE

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, design, performance and technological characteristics. This 510(k) is being submitted for an expansion of the Indications for Use to include benign gynecologic procedures as defined below.

Aspect	**Versius Surgical System (Versius plus), Predicate Device K252111**	**Versius Surgical System (Versius plus), Subject Device**
Device Name	Versius Surgical System	Versius Surgical System
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 general surgery for cholecystectomy as well as for gynecologic surgery for benign total hysterectomy, oophorectomy, salpingectomy, adnexectomy, ovarian cystectomy, and lysis of adhesions.

The intended use of the Versius Surgical System is consistent with and fully supports the specific Indications for Use. The system provides robotic assistance for the precise and accurate controlled manipulation of endoscopic surgical instruments used in soft-tissue surgical procedures. The functional capabilities described such as grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, and suturing represent the fundamental tasks required to perform the indicated general and gynecologic minimally invasive soft-tissue surgeries, including cholecystectomy and benign gynaecologic procedures.

Contraindication

Use of the Monopolar Curved Scissors is contraindicated in gynecologic surgery due to the risk of thermal injury from insulating sleeve damage. The use of Bipolar Graspers, monopolar hook, and non-energized Curved Scissors are recommended for these procedures.

VII. TECHNOLOGICAL CHARACTERISTICS

The Versius Surgical System that is the subject device of this 510(k) submission has no substantial differences from the predicate device in terms of technological characteristics.

VIII. PERFORMANCE DATA

The subject device is identical to the predicate device in 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.

In addition, pre-clinical testing in acute and chronic porcine models, originally performed to demonstrate the safety and efficacy of the predicate system, is applicable to the Versius Surgical Robotic System for robotic-assisted hysterectomy.

IX. CLINICAL

A single center, multi-surgeon single arm cohort study was conducted to confirm the preclinical safety and performance of CMR Surgical System in gynaecology procedures of total robotic assisted hysterectomy and/or salpingo-oophorectomy.

Forty-five (45) female patients underwent gynaecological surgery in this study. 30 of them had total hysterectomy (with or without salpingectomy /oophorectomy), while the remining 15 underwent unilateral or bilateral salpingo-oophorectomy. All participating patients were of Caucasian-European origin.

TLH patients had mean age of 50.8 years (range 37-66) and a mean BMI of 27.5 kg/m2 (range 17.3-36.7). Twenty-one patients (70%) had at least one comorbidity and 18 (60%) had a history of abdominal / pelvic surgery. One patient (3.3%) had American Society of Anaesthesiologists (ASA) status of I, 23 (76.7%) had ASA status of II, while 6 (20%) patients had ASA status of III.

USO/BSO patients had mean age of 50.4 years (range 22-74) and mean BMI of 27.5 kg/m2 (range 19.2-35.7). Eleven patients (73.3%) had at least one comorbidity, ten of whom had a history of abdominal / pelvic surgery. Twelve patients (80%) had ASA Status of II, while the remaining 3 (20%) had ASA status of III.

All 45 procedures (100%) were completed successfully using the Versius Surgical System without conversion to alternative surgical methods. Subjects were followed for up to 42 days post-procedure to evaluate surgical and clinical outcomes.

In the TLH cohort, 27 of 30 subjects (90%) experienced no intraoperative or postoperative adverse events. Three adverse events were reported in three subjects (10%): two intraoperative and one postoperative. Two not related to the device events (6.7%) were classified as serious and resulted in extended hospitalization. One intraoperative event was possibly associated with a tear in the insulating sleeve of a Versius instrument.

In the salpingo-oophorectomy cohort, 14 of 15 subjects (93.3%) had no intraoperative or postoperative adverse events. One non-serious, postoperative adverse event occurred up to 30 days after surgery and was not related to the device. The study met all predefined primary safety and clinical performance endpoints for robot-assisted TLH, salpingectomy, and/or oophorectomy with the Versius Surgical System. One intraoperative event was potentially associated with an insulation sleeve tear on the Monopolar Curved Scissors. The resulting risk is addressed by the contraindication in Section VI.

X. CONCLUSION

Based on the information provided in this submission, the Versius Surgical System has been demonstrated to be substantially equivalent to the currently legally marketed predicate device. The comparative analysis and clinical data support that there are no significant differences that raise new questions of safety or effectiveness.