October 11, 2024

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

Re: DEN230078
Trade/Device Name: Versius Surgical System
Regulation Number: 21 CFR 878.4964
Regulation Name: Modular electromechanical surgical system
Regulatory Class: Class II
Product Code: SCV
Dated: November 21, 2023
Received: November 21, 2023

Dear Michael Daniel:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Versius Surgical System, a prescription device under 21 CFR Part 801.109 with the following indications for 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 indicated for adult patients 22 years of age and older, eligible for soft tissue minimal access surgery, for cholecystectomy.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Versius Surgical System, and substantially equivalent devices of this generic type, into Class II under the generic name modular electromechanical surgical system.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On November 21, 2023, FDA received your De Novo requesting classification of the Versius Surgical System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Versius Surgical System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Versius Surgical System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Electrical fault, electromagnetic interference, mechanical fault, or system malfunction resulting in: • Tissue injury • Electric shock • Prolonged procedure time.	Clinical performance testing Postmarket surveillance Animal performance testing 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: • Re-operation • Hematoma • Tissue injury • Increased blood loss	Clinical performance testing Postmarket surveillance Animal performance testing Training Annual reporting Human factors testing Labeling

Risks to Health	Mitigation Measures
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

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

In order to satisfy special control (1) above, FDA has determined that you must collect and report postmarket surveillance data acquired under anticipated conditions of use to demonstrate that the device performs as intended when used to analyze data from the US patient population. Specifically, you must conduct postmarket clinical validation performance testing of the Versius Surgical System device in patients from demographic groups representative of the U.S. population, to include populations who had limited representation in the premarket study (e.g., African American, Asian, etc.) including populations which have combinations of comorbidities similar to the general U.S. population.

Additionally, the postmarket clinical testing must evaluate the proficiency of novice and experienced surgeons as measured in part by the same major procedural endpoints used in the premarket clinical studies. You must also evaluate how these endpoints change with increased surgical experience using the Versius Surgical System. This information is needed to demonstrate the training program raises the proficiency of all users to the level necessary to perform the labeled surgical procedure safely and effectively.

FDA expects that the postmarket clinical validation performance testing will include a clinically and statistically justified study sample size to confirm that performance of the device in postmarket use is not inferior to the performance observed in the pre-market study for the studied subgroup(s) or the overall population. The study should enroll a representative range of subjects with overrepresentation of patient demographics not present in the premarket data set.

Within 30 days of receipt of this order, you must submit a complete study protocol for your study as described above. FDA expects to work with you to approve your study protocol within 60 days of this order. Your submission should be clearly labeled as a “De Novo Postmarket Study Protocol” and submitted to the Agency as specified below. Please reference the De Novo number above to facilitate processing. If there are multiple protocols being finalized after granting of this De Novo request, 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 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 study report should be submitted to the Agency as specified below, identified as a "De Novo Postmarket Study Report" in accordance with how the study is identified above, and bearing the applicable De Novo 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.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the modular electromechanical surgical system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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 De Novo number to facilitate processing.

De Novo Postmarket Surveillance
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.

If you have any questions concerning the contents of the letter, please contact Albert Yee at Albert.Yee@fda.hhs.gov.

Sincerely,

BLETA VUNIQI -S

Digitally signed by BLETA VUNIQI -S
Date: 2024.10.11 13:59:10 -04'00'

for Binita Ashar, M.D., M.B.A., F.A.C.S., M.A.M.S.E.
Director
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health