October 30, 2026

Virtuoso Surgical, Inc.
Richard Hendrick
General Counsel & Chief Administrative Officer
4560 Trousdale Dr.
Nashville, Tennessee 37204

Re: DEN250054
Trade/Device Name: Virtuoso Endoscopy System
Regulation Number: 21 CFR 878.4967
Regulation Name: Electromechanical surgical system for endoluminal surgical procedures
Regulatory Class: Class II
Product Code: SJS
Dated: September 30, 2025
Received: December 4, 2025

Dear Richard Hendrick:

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 Virtuoso Endoscopy System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Virtuoso Endoscopy System is indicated for urologic surgery in the bladder where a transurethral approach is appropriate. The Virtuoso Endoscopy System is indicated for en bloc resection of bladder lesions in adult patients to obtain tissue samples, including detrusor muscle, to assist in the diagnostic evaluation of cancer of the bladder. It is intended to be used by trained surgeons in an operating room environment.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Virtuoso Endoscopy System, and substantially equivalent devices of this generic type, into Class II under the generic name electromechanical surgical system for endoluminal surgical procedures.

FDA identifies this generic type of device as:

> **Electromechanical surgical system for endoluminal surgical procedures**. An electromechanical surgical system for endoluminal surgical procedures is a software-controlled electromechanical

system with human/device interfaces that allows a qualified user to perform surgical procedures using robotically-controlled instruments passed through an endoscope into a body lumen.

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 December 4, 2025, FDA received your De Novo requesting classification of the Virtuoso Endoscopy System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Virtuoso Endoscopy 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 Virtuoso Endoscopy 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 disturbances, mechanical fault, or system malfunction resulting in: • Tissue/organ injuries (e.g., hollow organ perforation, endoluminal trauma, increased blood loss) • Incomplete procedure • Electric shock • Prolonged procedure time • Electrical/thermal burn	Electromagnetic compatibility testing Electrical safety testing Software verification, validation, and hazard analysis Non-clinical performance testing Clinical performance testing Postmarket surveillance Labeling Annual reporting
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing
Infection	Sterility validation Reprocessing validation Shelf life testing Labeling

Risks to Health	Mitigation Measures
Use error leading to prolonged procedure time or patient harm resulting in: • Tissue/organ injuries (e.g., hollow organ perforation, endoluminal trauma, increased blood loss) • Reoperation • Incomplete procedure • Disease progression	Human factors testing Training Labeling Clinical performance testing Postmarket surveillance Non-clinical performance testing Annual reporting

In combination with the general controls of the FD&C Act, the electromechanical surgical system for endoluminal surgical procedures is subject to the following special controls:

(1) Premarket clinical performance testing, or a combination of premarket clinical performance testing and postmarket surveillance (in accordance with special control (2)), must include the following:
   (i) Objective performance measures (e.g., rate and number of conversions to other surgical modalities, rate of device related intraoperative and postoperative adverse events (including tissue injury, hollow organ perforation, endoluminal trauma, rate of intraoperative and postoperative complications, incomplete procedures, re-operations and increased blood loss), and their severity, cause, and outcomes) must be reported with relevant descriptive comparator performance measures.
   (ii) The data must demonstrate accurate and precise control of attached surgical instruments within a body lumen in a range of clinical conditions relevant to the device's intended use (e.g., demonstration of complete and adequate specimen acquisition).
   (iii) The test dataset must include data collected from a patient population representative of the intended patient population under anticipated conditions of use.

(2) Data obtained from postmarket surveillance must demonstrate the data described in special control (1)(i)-(iii), in consideration of the premarket data obtained in accordance with special control (1), unless FDA determines, based on the totality of the premarket data, that data from postmarket surveillance is not required for such demonstration. Such postmarket surveillance must be conducted per a protocol determined appropriate by FDA for such demonstration (in consideration of the premarket data obtained in accordance with special control (1)), and must include initiation, enrollment, and reporting requirements to ensure timely periodic updates to FDA on postmarket surveillance progress and outcomes.

(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 assessment must demonstrate that the user can correctly use the device system across all intended use environments with the provided instructions and training materials, including safe manual retraction and emergency release of the surgical instruments and endoscope from the body lumen and safe patient access during both normal operating conditions and emergency situations.

(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 for the representative specific procedures was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of the patient's underlying disease or condition, 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 summary of any completed postmarket surveillance data collected as required by special control (2), including updated labeling to accurately reflect outcomes observed in postmarket surveillance.

(7) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include:
- (i) Evaluation of the device’s ability to successfully complete the intended surgical tasks (e.g., sufficient reach and workspace) when using robotically controlled surgical instruments passed through an endoscope into an anatomically representative model lumen system (e.g., cadaver);
- (ii) Device motion accuracy and repeatability, including system positioning, endoscope translation and rotation, and instrument motion;
- (iii) System testing;
- (iv) Instrument reliability;
- (v) User-device interface performance;
- (vi) Workspace access verification testing; and
- (vii) 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 controls (1) and (2) above, and in consideration of the premarket clinical information provided, FDA has determined that you must conduct postmarket surveillance. FDA has determined that to be an appropriate protocol as described in special control (2), your protocol for conducting such postmarket surveillance must collect and report postmarket surveillance data with the Virtuoso Endoscopy System acquired under anticipated conditions of use and in the intended U.S. patient population, with a justified sample size. The protocol must include:

- Patients from demographic groups representative of the U.S. population, including populations which have combinations of comorbidities similar to the general U.S. population.

- Evaluation of the proficiency of novice and experienced surgeons as measured in part by the major procedural endpoints used in the premarket clinical studies, consistent with special control (1)(i)(iii)). This information is needed to evaluate the effectiveness of the training program in raising the proficiency of all users to the level necessary to perform the labeled surgical procedure safely and effectively.

Within 30 days of receipt of this order, you must submit a complete study protocol for your study(ies) as described above. FDA expects to work with you to determine that your study protocol is appropriate as described in special control (2) 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 the study protocol is determined to be appropriate, 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 study progress reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date the protocol is determined to be appropriate,, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting enrollment status reports every three (3) months in addition to your annual postmarket study progress reports, until enrollment has been completed or FDA notifies you otherwise.
- Submit the final postmarket study report three (3) months from study completion (i.e., last subject's last follow-up date).

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

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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).

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 electromechanical surgical system for endoluminal surgical procedures 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 Management System Regulation (QMSR) (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).

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.

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.

Postmarket Mandated Studies Program

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

If you have any questions concerning the contents of the letter, please contact Mahsan BakhtiariNejad at 301-796-0018.

Sincerely,

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Julie Morabito, Ph.D.
Director
DHT4A: Division of General Surgery Devices
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