July 21, 2026

Auris Health, Inc., part of Johnson & Johnson MedTech
Anna (Inna) Libman
Sr. Director, Regulatory Affairs
5490 Great American Pkwy.
Santa Clara, California 95054

Re: DEN250068
Trade/Device Name: OTTAVA™ Robotic Surgical System
Regulation Number: 21 CFR 878.4966
Regulation Name: Integrated operating table-electromechanical surgical system
Regulatory Class: Class II
Product Code: SIR
Dated: December 18, 2025
Received: December 18, 2025

Dear Anna (Inna) Libman:

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 OTTAVA™ Robotic Surgical System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The OTTAVA™ Robotic Surgical System is intended to assist in the accurate control of endoscopic Instruments, Endoscopes, and Accessories for visualization and manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, suturing, and to allow the surgical staff to reposition the patient by adjusting the Table without undocking during upper abdominal general laparoscopic surgical procedures in accordance with the representative, specific procedures set forth in the Instructions for Use. The System is indicated for adult use. It is intended to be used by trained physicians in an operating room environment.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the OTTAVA™ Robotic Surgical System, and substantially equivalent devices of this generic type, into Class II under the generic name integrated operating table-electromechanical surgical system.

FDA identifies this generic type of device as:

> **Integrated operating table-electromechanical surgical system**. An integrated operating table-electromechanical surgical system is a software-controlled electromechanical platform, consisting of

a surgical table with integrated robotic arms and table motion capability, that enables a qualified user to perform surgical techniques during minimally invasive and laparoscopic surgical procedures. The surgical table can be used for open surgical procedures independent of the robotic platform.

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 18, 2025, FDA received your De Novo requesting classification of the OTTAVA™ Robotic Surgical System.

The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the OTTAVA™ Robotic 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 OTTAVA™ Robotic 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**
Electric fault, electromagnetic interference, mechanical fault, or system malfunction resulting in: • Tissue/organ injury • Electric shock • Prolonged procedure time • Electrical/thermal burn	Clinical performance testing Postmarket surveillance In vivo performance testing Non-clinical performance testing Electrical safety testing Electromagnetic compatibility testing Software verification, validation, and hazard analysis Labeling Annual reporting
Infection	Sterilization validation Reprocessing validation Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing

Risks to Health	Mitigation Measures
Use errors leading to patient harm or prolonged procedure time: • Re-operation • Tissue/organ injury • Hematoma • Increased blood loss • Electrical/thermal burn	Clinical performance testing Postmarket surveillance In vivo performance testing Non-clinical performance testing Human factors testing Training Labeling Annual reporting

In combination with the general controls of the FD&C Act, the integrated operating table-electromechanical surgical system 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 adverse events (including tissue injury, hematoma, and increased blood loss), and their severity, cause, and outcomes) must be reported with relevant descriptive comparator performance measures.
   (ii) The data must demonstrate the performance of the device for providing accurate and precise control of attached surgical instruments in range of clinical conditions relevant to the device's intended use.
   (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, in consideration of the premarket data obtained in accordance with special control (1), that the device performs 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 to demonstrate that the device performs as intended. Such postmarket surveillance must be conducted per a protocol determined appropriate by FDA to demonstrate that the device performs as intended (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 post-market surveillance progress and outcomes.

(3) Animal performance testing must evaluate the extent of port site trauma due to repositioning of table during surgical procedures when utilizing robotic minimally invasive and laparoscopic approaches

(4) 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.

(5) 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.

(6) 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 patient access during normal operating conditions and emergency situations, and effects arising from the integrated nature of the operating table and robotic surgical arms.

(7) 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.

(8) 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 repeatability;
- (ii) System testing;
- (iii) Instrument reliability;
- (iv) Crosstalk;
- (v) Table motion control;
- (vi) Thermal effects on tissue;
- (vii) User-device interface performance;
- (viii) Workspace access testing; and
- (ix) Performance testing with compatible devices.

(9) Software verification, validation, and hazard analysis must be performed.

(10) Electromagnetic compatibility and electrical, thermal, and mechanical safety testing must be performed.

(11) Performance data must demonstrate the sterility of all patient-contacting device components.

(12) 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.

(13) Performance data must validate the reprocessing instructions for the reusable components of the device.

(14) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(15) Performance data must demonstrate that all patient-contacting components of the device are non-pyrogenic.

(16) 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 consideration of the totality of the data from premarket clinical performance testing obtained in accordance with special control (1), FDA has determined that data from postmarket surveillance is not required to demonstrate that the OTTAVA™ Robotic Surgical System performs as intended.

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.

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 integrated operating table-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 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).

If you have any questions concerning the contents of the letter, please contact Sadia Hasan at 240-402-3140.

Sincerely,

JULIE A. MORABITO -S
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Julie Morabito, Ph.D.
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