July 19, 2023

Hogan Lovells US LLP
Galen Robotics
c/o John J. Smith, M.D., J.D.
Partner
555 Thirteenth Street, NW
Washington, DC 20004

Re: DEN220047
Trade/Device Name: Galen ES Robotic Surgical Assistant Platform, Galen ES
Regulation Number: 21 CFR 874.4460
Regulation Name: Cooperative powered surgical assist device for ENT surgery
Regulatory Class: Class II
Product Code: QXG
Dated: July 21, 2022
Received: July 22, 2022

Dear Dr. Smith:

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 Galen ES Robotic Surgical Assistant Platform, Galen ES, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Galen ES is intended to assist in the movement of the specified Integra Jako Micro Laryngeal Alligator Forceps to a surgeon-selected position within a surgical field and remain in place until moved elsewhere by the operator. The Galen ES is indicated to be used in rigid microlaryngeal procedures where the specified Jako Micro Laryngeal Alligator Forceps would be utilized by an experienced trained otolaryngologist performing microlaryngeal surgery in an operating room environment in patients at least 18 years old.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Galen ES Robotic Surgical Assistant Platform, Galen ES, and substantially equivalent devices of this generic type, into Class II under the generic name cooperative powered surgical assist device for ENT surgery.

FDA identifies this generic type of device as:

> **Cooperative powered surgical assist device for ENT surgery**. A cooperative powered surgical assist device for ear, nose, and throat (ENT) surgery is a device that facilitates ENT surgical procedures, including instrument placement. The device works in conjunction with the surgeon's movements to assist with precise and stable positioning of an instrument while maintaining the surgeon’s direct physical control of the instrument.

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 July 22, 2022, FDA received your De Novo requesting classification of the Galen ES Robotic Surgical Assistant Platform, Galen ES. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Galen ES Robotic Surgical Assistant Platform, Galen ES 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 Galen ES Robotic Surgical Assistant Platform, Galen ES 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**
Injury to anatomic structures resulting in bleeding or loss of function	Simulated use testing Human factors evaluation Non-clinical performance testing Software verification, validation and hazard analysis Labeling Electromagnetic compatibility (EMC) testing Electrical safety testing Thermal safety testing Biocompatibility evaluation
Inability to remove the device expeditiously (e.g., if device becomes sluggish or frozen) resulting in: • Lack of sufficient control of bleeding • Prolonged time for removal and delayed access to critical structures	Simulated use testing Non-clinical performance testing Software verification, validation and hazard analysis Labeling Electromagnetic compatibility (EMC) testing Electrical safety testing
Infection	Labeling Simulated use testing Sterilization validation Shelf life testing

In combination with the general controls of the FD&C Act, the cooperative powered surgical assist device for ENT surgery is subject to the following special controls:

(1) Simulated use testing must demonstrate that the device performs as intended under anticipated conditions of use to successfully assist in the indicated surgery, including:
    (i) Testing in a simulated hospital environment with an anatomically relevant model;
    (ii) Compatibility testing of all indicated instruments;
    (iii) Human factors/usability evaluation; and
    (iv) Validation of device use by surgeons, including:
        (A) The user interface and controller(s);
        (B) Compatibility with the ranges of surgeon-applied forces, torques, speeds, and motion; and
        (C) Time required for emergency removal of the device and associated instruments in the event of power loss or device failure.
(2) Non-clinical performance testing must demonstrate hardware and system verification, including verification of critical parameters (including minimum and maximum forces, torques, speeds, and range of motion).
(3) Software verification, validation, and hazard analysis must be performed for any software components of the device.
(4) Performance testing must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device.
(5) All parts or components of the device that enter the sterile field must be demonstrated to be sterile.
(6) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.
(7) All patient-contacting components of the device must be demonstrated to be biocompatible.
(8) Labeling must include:
    (i) Identification of compatible instruments;
    (ii) A statement about any training needed prior to use of the device;
    (iii) A summary of all relevant performance testing, including simulated use testing; and
    (iv) Reprocessing instructions for reusable device components.

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

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 cooperative powered surgical assist device for ENT surgery 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).

If you have any questions concerning the contents of the letter, please contact Vasant Dasika, Ph.D., at 301-796-5365.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health