

**DE NOVO CLASSIFICATION REQUEST FOR
GALEN ES COOPERATIVE SURGICAL ASSISTANT PLATFORM, GALEN ES**

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 874.4460

CLASSIFICATION: Class II

PRODUCT CODE: QXG

BACKGROUND

DEVICE NAME: Galen ES Cooperative Surgical Assistant Platform, Galen ES

SUBMISSION NUMBER: DEN220047

DATE DE NOVO RECEIVED: July 22, 2022

SPONSOR INFORMATION:

Galen Robotics
1100 Wicomico St., Ste. 725
Baltimore, Maryland 21230

INDICATIONS FOR USE

The Galen ES Cooperative Surgical Assistant Platform, Galen ES is indicated as follows:

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.

LIMITATIONS

The sale, distribution, and use of the Galen ES are restricted to prescription use in accordance with 21 CFR 801.109.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Galen ES (see Figure 1 and Figure 2) is a cooperatively-controlled surgical assistant platform (i.e., designed to be controlled by direct user interaction with the surgical instrument), intended to assist in the manipulation of the Integra Jako Micro Laryngeal Alligator Forceps (Integra Part# 3731042 serrated 9.0mm, straight 9.25 inch (235 mm)) (see Figure 3).

NOTE: The Integra Jako Micro Laryngeal Alligator Forceps will not be provided with the system.

The Galen ES is designed to work with the surgeon by sensing the physical forces and movements applied by the surgeon to the Integra Jako Micro Laryngeal Alligator Forceps connected to the Galen ES and successively moving the instrument in a manner consistent with the forces applied.

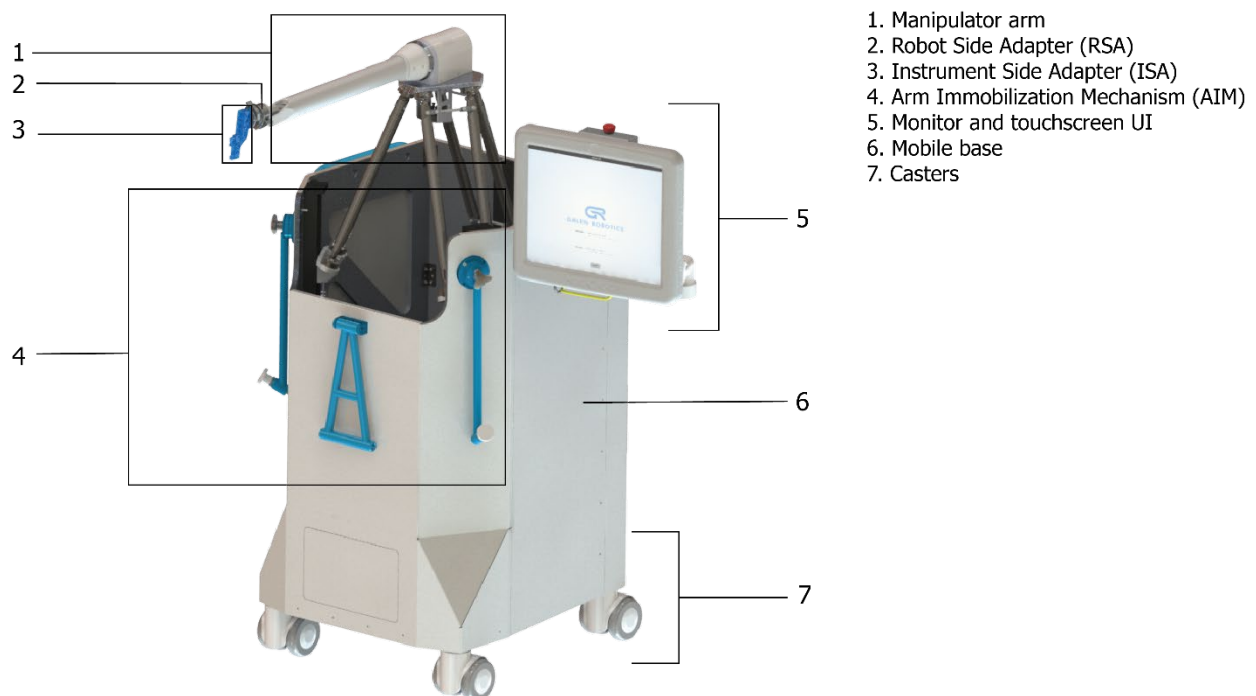


Figure 1: Galen ES Cooperative Surgical Assistant Platform (Front View)

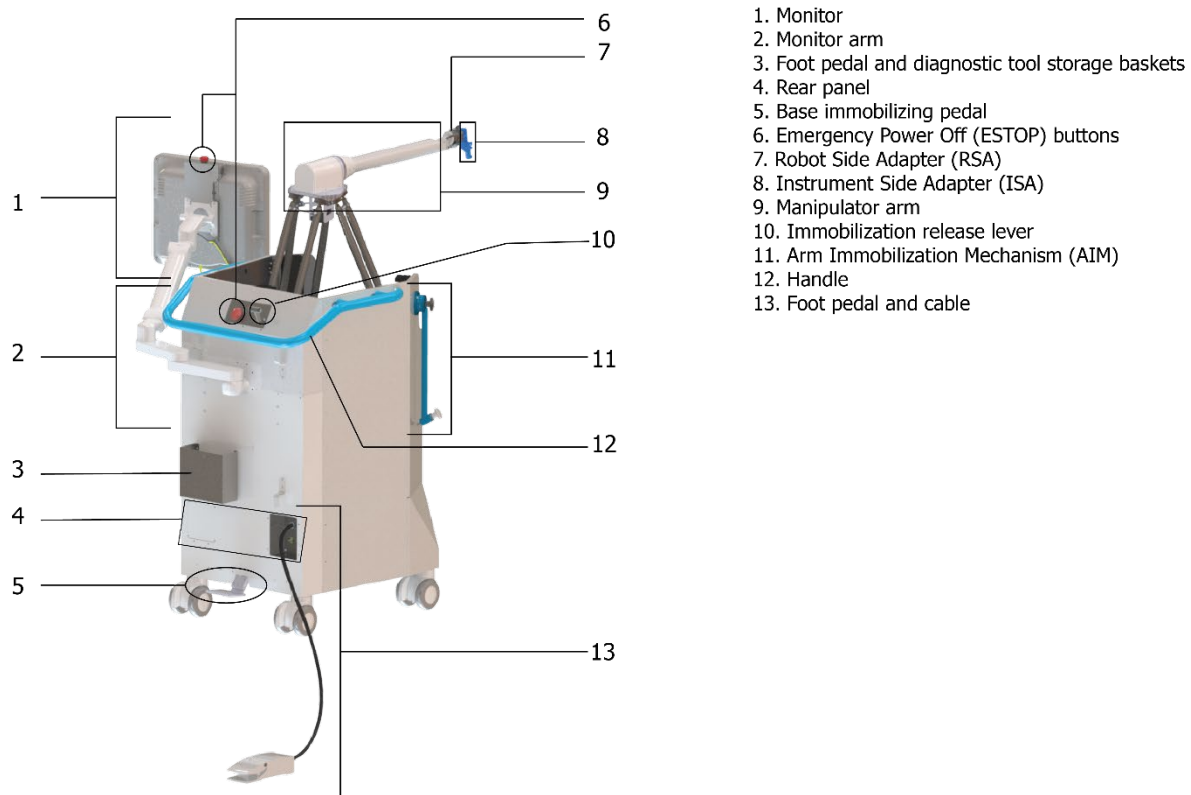


Figure 2: Galen ES Cooperative Surgical Assistant Platform (Rear View)

The following accessories are included with the Galen ES:

1. Two (2) sterile, single-use surgical drapes
 - a. One (1) to cover the device's manipulator arm and mobile base,
 - b. One (1) to cover the device's monitor and touchscreen
2. One (1) Robot Side Adapter (RSA)
3. One (1) RSA Sterilization Tray
4. One (1) Instrument Side Adapter (ISA). The ISA is a sterile, single-use accessory, which connects to the device's manipulator arm via the Robot Side Adapter (RSA), with the intended use of holding the Jako forceps

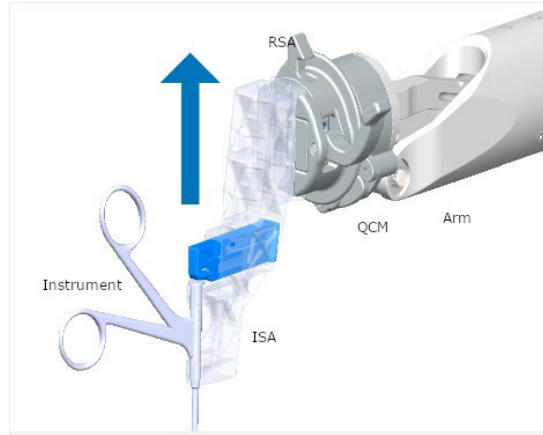


Figure 3: Jako forceps which have been attached to the ISA. The ISA is coupled to the RSA which is attached to the Robotic Arm. The ISA (with attached forceps) can be manually removed from the arm (if necessary).

Table 1 provides a high-level description of the critical system components and accessories of the device.

Table 1: Critical System Components and Accessories Relevant to Treatment of a Disease or Condition

System Component or Accessory	Description
1. Manipulator Arm (Figure 1-1)	The robotic element containing several components that allow the device to function as a robotic assistant for the surgeon: • The Force-Torque sensor reads the forces and torques applied to the forceps attached to the device, allowing the device to sense the actions of the surgeon. • The motors drive the motion of the arm, which allows the device to physically move the instrument in a manner consistent with the forces applied. • The encoders sense the position of the arm, allowing the device to know its current location and make movements. These elements work in concert, allowing the surgeon to experience improved instrument stability and control, as they manipulate the instrument in tight, narrow-corridor procedures.
2. Robot Side Adapter (RSA) (Figure 1-2)	A removable and sterilizable accessory attached to the manipulator arm that serves as the attachment point for the ISA.
3. Instrument Side Adapter (ISA) (Figure 1-3)	The ISA is a removable one-time use accessory that attaches to the RSA. It serves as the attachment point for the forceps that are used during the surgical procedure. The ISA allows the forceps to be securely attached to the device and ensures a secure attachment to the RSA. The ISA is intended as a one-time-use disposable, simplifying post-procedural clean up and sterilization.
4. Arm Immobilization Mechanism (AIM) (Figure 1-4)	Protects the manipulator arm and force sensor from damage during transportation and storage.

System Component or Accessory	Description
5. Monitor with touchscreen (Figure 1-5)	Displays information and receives inputs Guides the supporting operators through the set up and shut down procedures Allows the surgeon to change device settings Informs the surgeon when the device encounters an error.
6. Mobile Base (Figure 1-6)	Contains the device's components and serves as a rigid frame to protect them from physical damage.
7. Casters (Figure 1-7)	Attach to the bottom of the chassis and allow the device to be moved.
8. Emergency (ESTOP) buttons (Figure 2-6)	When an ESTOP is engaged, the power to the manipulator arm motors is removed, and brakes on the delta stage portion of the manipulator arm are engaged. This serves to lock the manipulator arm in place.
9. Base-immobilizing pedal (Figure 2-5)	When the Base Immobilizing Pedal is depressed, it activates the Base Immobilizing Actuator, locking the device in a fixed position, preventing it from being moved on its casters. The immobilization of the Device is hydraulically-actuated and does not require electrical power to be engaged or disengaged. This ensures the device remains in the same position during the procedure.
10. Immobilization release lever (Figure 2-10)	Disengages the Base-immobilizing actuator, allowing the device to be moved on its casters.
11. Foot pedal and cable (Figure 2-13)	When the foot pedal is engaged, the power to the manipulator arm is enabled, allowing movement of the manipulator arm. This allows the surgeon to use the device to manipulate the attached forceps.

Third-party Devices

The Galen ES is intended to be used with the following third-party devices (Table 2), which are not provided with the Galen ES System, to enable the subject device to perform its intended purpose.

Table 2: Third-Party Devices Not Provided with the Galen ES System

Component	Description
Alligator Forceps	Jako Micro Laryngeal Alligator Forceps Serrated 9.0mm, straight 9.25 inch (235 mm) – Integra Part# 3731042

SUMMARY OF NONCLINICAL/BENCH STUDIES

Non-clinical performance tests were conducted to demonstrate that the Galen ES will perform as anticipated for its intended use and to mitigate the risks to health as outlined below.

BIOCOMPATIBILITY/MATERIALS

Biocompatibility testing was not performed because the device is not intended to have either direct or indirect contact with the body.

SHELF LIFE/STERILITY

The purpose of the sterility, reprocessing, packaging, and shelf-life evaluations were to mitigate the risk of infection for the patient. The device's RSA cleaning instructions were validated to achieve a Sterility Assurance Level (SAL) of 10^{-6} . The ISA and surgical drapes are single-use accessories, which are individually packaged and sterilized via Ethylene Oxide (EO) to a SAL of 10^{-6} . The packaging was validated via a protocol compliant with the requirements of FDA-recognized consensus standards.

All testing and results met the acceptance criteria and/or standards.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

Electromagnetic compatibility (EMC) and electrical safety of the device was evaluated to mitigate the risk of electrical fault resulting in injury to patient or user.

The following Electrical/ Mechanical/Thermal Safety, and EMC testing has been performed:

Identifier	Title
IEC 60601-1:2005 Ed.3+ A1	General Requirements for Basic Safety and Essential Performance

Identifier	Title
IEC 60601-1-2:2014 Ed.4	General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances
IEC 60601-1-6:2010 Ed.3+A1	General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
IEC 80601-2-77:2019 Ed.1	Particular Requirements for the Basic Safety and Essential Performance of Robotically Assisted Surgical Equipment

All testing and results met the acceptance criteria of the above standards.

SOFTWARE

The software was evaluated to mitigate the risks of electrical, and mechanical faults associated with the device not working as intended due to the programming, or due to system malfunctions.

The Galen ES Surgical System Software consists of two (2) separate modules – the Galen ES Control software and the Galen ES GUI software. The Galen ES GUI software presents the main user interface for the Galen ES Surgical System and runs on the touchscreen computer of the Galen ES Surgical System. The remainder of the software modules control the functions of their respective hardware.

The Galen ES Surgical System software was developed in accordance with the following FDA guidance documents and standards:

Identifier	Title
FDA Guidance Documents	
General Principles of Software Validation, issued January 11, 2002	
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005	
Off-the-Shelf Software Use in Medical Devices, issued September 27, 2019	
Software	
IEC 62304:2006 Ed.1+A1	Medical device software – Software life-cycle processes
Risk Management	
ISO 14971:2019	Medical devices - Application of risk management to medical devices

Galen considers the software to be a major level of concern (LOC) because failure or latent flaw could directly result in death or serious injury to the patient or operator. Furthermore, a failure or latent flaw could indirectly result in death or serious injury of

the patient or operator through incorrect or delayed information or through the action of a healthcare provider.

All testing and results met the acceptance criteria and/or standards.

CYBERSECURITY

The Galen ES Surgical System was evaluated for cybersecurity risks consistent with the FDA guidance document titled, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued October 2, 2014.

Acceptable information was provided per the above referenced cybersecurity guidance about software malfunctions, malicious or otherwise, which could lead to patient harm, or the ability to control/manipulate/affect the device remotely, whether by design or not.

PERFORMANCE TESTING - BENCH

The following bench tests were performed to mitigate the risks of electrical, and mechanical fault resulting in injury to patient or user, tissue perforation and/or injury due to system malfunction, user error resulting in patient injury:

- Force sensor accuracy
- Torque sensor accuracy
- System performance verification:
 - Degrees of freedom
 - Motion actuation
 - Limit sensing
 - Passive instrument holding
 - Device immobilization
 - Recovery from unintended power loss

The bench tests characterize device performance and design verification for the Galen ES.

These bench tests were conducted using verification protocols including objective acceptance criteria. Bench testing was also conducted on a preliminary version of the device to support reduction of both surgeon fatigue and tremor. All bench testing met acceptance criteria.

PERFORMANCE TESTING - CADAVER

Human Factors Engineering

Human Factors Engineering Testing was performed to mitigate the risks of device-specific use error or of mechanical or electrical faults that result in injury to the patient or user. Usability testing was performed in accordance with FDA guidance document titled,

Applying Human Factors and Usability Engineering to Medical Devices, issued February 3, 2016, to demonstrate the device usability.

Purpose

The usability validation study was conducted to evaluate whether the Galen ES System, as designed, supports safe use by representative users when performing rigid microlaryngeal procedures in cadaver. The validation testing consisted of the following objectives:

1. Evaluate whether typical users can safely and effectively interact with the device
2. Confirm that use-related risks have been appropriately captured and assessed in the Use Related Risk Analysis (URRA) or uncovering any previously unforeseen use errors
3. Assess the effectiveness of the risk mitigation measures that have been applied during the Galen ES' design stage
4. Identify and validate the critical tasks and sub-tasks that were a part of the device use training program provided in the field.

Study Design

A total of 47 individuals participated in the human factors testing; 16 were setup operators and 31 were operating surgeons. The human factors testing spanned two studies: a usability study (with 16 surgeons) and a followup confirmatory usability study (with 15 surgeons). The confirmatory usability study was conducted to more directly test for and ensure device usability from a safety perspective, including in emergent situations (simulated hemorrhage) requiring immediate device removal. The setup operators' years of clinical experience ranged from 0.5 to 41 years, while the operating surgeons' clinical experience ranged from 1 to 35 years.

The testing was conducted in a simulated operating room environment and involved device setup, diagnostic testing, procedure execution, and device shutdown, as well as emergency procedures involving critical tasks.

Participants underwent a training program that mirrored the intended user training that will be provided to customers, except on a condensed schedule. This program emphasized practicing and performing critical tasks to gain familiarity with the device before entering the study room. An enforced 1-hour training decay period occurred between completion of the training program and commencement of the study session.

Twenty seven (27) tasks were defined for surgeons in a simulated hospital environment. Tasks included: Selecting correct instrument on user interface, Working ergonomically with the device without problems, Completing workflow, Recognizing critical information, e.g., if the device moved to the edge of its bounds. Three clinically relevant laryngoscopy tasks were also included in a confirmatory usability study with 15 surgeon participants: 1) Anatomical mapping and fiducial Identification, 2) Vocal cord

manipulation, and 3) Hemorrhage simulation and emergency Galen ES removal and logging of device removal time.

Evaluation

Successful performance of a task was defined as follows:

- Actions performed by the participant were in agreement with the details listed in the expected results column of the study protocol
- Said actions were completed on the first attempt performed by the participant

Results

Human factors testing demonstrated that all critical tasks were completed, and acceptance criteria were met by all users. The Galen ES device has been found to be safe and effective for the intended users, uses, and use environment. The participants provided valuable feedback through their execution of the tasks set out by the validation protocol, as well as the subsequent critiques provided during debriefing interviews and questionnaires. Results showed participants were able to perform all aspects of a microlaryngeal procedure appropriate for use with the Galen ES system. Although some tasks were determined to be difficult, analyses revealed that no new hazardous use scenarios were identified, and no critical task was modified.

The emergency removal of the forceps and Galen ES from the surgical field and logging the removal time in a simulated emergency (bleeding) event was conducted in the confirmatory usability study. On average, surgeon participants (n=15) in the followup usability study required 14 seconds to remove the Jako forceps from the airway after initiation of a simulated bleeding event began; 9 participants took less than 10 seconds, 3 participants took between 10 and 20 seconds, and the remaining 3 participants took longer than 20 seconds (longest time was 61 seconds). This is considered clinically acceptable because these time frames would be consistent with removal of a manual surgical forceps tool during manual surgery, i.e., without the use of a cooperative powered surgical assist device.

Pediatric Extrapolation

In this De Novo request, existing data were leveraged to support the of the proposed device in the 18-21 years old pediatric subpopulation. It was appropriate to indicate the device for individuals 18 and older because patients aged 18 to 21 do not carry additional differences or risks relative to the adult patient population for this device.

TRAINING PROGRAM DESIGN

The training program for the Galen ES System is comprised of a series of modules to ensure that each user understands each component of the system and thoroughly comprehends the various workflows involved in operating the device.

The training program includes the following sections:

1. Didactic Training Module: A slideshow presentation that includes an introduction to the device's technology and operation. This includes a technical overview of the robot, functional aspects of the system, and troubleshooting tips.
2. Hands-on Training Module:
 - a. Specific training for nurses and technicians – this will include practicing tasks such as using the touchscreen, drapes, ISA, and RSA.
 - b. Specific training for surgeons – this will include practicing Galen-assisted procedures using a simulated patient anatomy bench model and cadaveric tissue.
3. Proctored Device Use: Following completion of the training the company will engage in 1 to 2 proctored procedures with the user where a company expert will be available to address any device-related questions during the procedure.

LABELING

Labeling for the Galen ES device includes the following:

- Identification of compatible surgical instruments
- Recommended training for the safe use of the device
- Summary of all relevant performance testing, including simulated use testing
- Reprocessing instructions for reusable device components

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a cooperative powered surgical assist device for ENT surgery and the measures necessary to mitigate these risks.

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	Simulated use testing Non-clinical performance testing Software verification, validation and hazard analysis Labeling Electromagnetic compatibility (EMC) testing Electrical safety testing

Risks to Health	Mitigation Measures
Prolonged time for removal and delayed access to critical structures	
Infection	Labeling Simulated use testing Sterilization validation Shelf life testing

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

Risks

The risks of the Galen ES device include injury to anatomic structures resulting in bleeding or loss of function, inability to remove the device expeditiously (e.g., if device becomes sluggish or frozen) resulting in lack of sufficient control of bleeding or prolonged time for removal and delayed access to critical structures, and infection. General risks of the Galen ES include injury to patients or users due to use error or electrical/mechanical faults. Use-related errors may also occur if surgeons or setup operators are insufficiently trained on safe and effective use of the device. These risks are mitigated (in part) with usability testing and non-clinical performance testing, labeling (including warnings and precautions) and training.

Benefits

The following probable benefits are identified for the Galen ES based on the data collected in the human factors studies or as demonstrated in bench testing:

1. Assist a surgeon in maneuvering and positioning the intended Jako forceps within the narrow surgical corridor presented during rigid microlaryngeal procedures,
2. Enables prolonged positioning of the Jako forceps in a specific position that is determined by the surgeon,
3. Moves in concert with the applied forces. Provides stability in the procedure by reducing user fatigue and tremor as demonstrated in bench testing, and
4. When used as indicated, frees hand of surgeon to utilize other instrument(s).

The usability studies conducted in support of this device provided data from 31 operating surgeons who performed simulated microlaryngeal procedures on cadaver. During these simulated procedures, all critical tasks were successfully completed and no significant events were encountered.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

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.

The probable benefits outweigh the probable risks for the Galen ES Cooperative Surgical Assistant Platform, or Galen ES. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Galen ES Cooperative Surgical Assistant Platform, Galen ES is granted and the device is classified as follows:

Product Code: QXG

Device Type: Cooperative powered surgical assist device for ENT surgery

Regulation Number: 21 CFR 874.4460

Class: II