DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2015

Gyrus ACMI Incorporated
Mr. Dolan Mills
Sr. Specialist, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K142759
Trade/Device Name: PK Cutting Forceps for ESG-400 workstation
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 4, 2014
Received: December 8, 2014

Dear Mr. Mills:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
PK Cutting Forceps for ESG-400 workstation

K142759

Indications for Use *(Describe)*
The PK Cutting Forceps are indicated for electrosurgical coagulation, mechanical cutting, and grasping of tissue during the performance of laparoscopic and open general surgical procedures when used in conjunction with the general purpose ESG-400 workstation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Gyrus ACMI, Inc.
PK Cutting Forceps for ESG-400 Workstation

General Information

Manufacturer:	Gyrus ACMI, Inc., an Olympus company 136 Turnpike Road Southborough, MA 01772-2104 Phone: 1-800-262-3540 Fax: 1-901-373-0260
Establishment Registration Number:	3003790304
Contact Person:	Dolan Mills Senior Specialist, Regulatory Affairs
Date Prepared:	September 24, 2014

Device Description

Classification Name:	Electrosurgical Cutting & Coagulation Device and Accessories
Regulatory Class	Class 2
Regulation Number	21 CFR 878.4400
Review Panel	General and Restorative Surgery Panel
Product Code	GEI
Trade Name(s):	PK Cutting Forceps, ESG PK Cutting Forceps, ESG PK CF
Generic/Common Name:	Electrosurgical cutting and coagulation device and accessories

Predicate Device

Gyrus ACMI Inc. HALO PKS Cutting Forceps: K100896
This predicate has not been subject to a design-related recall.

Product Description

The PK Cutting Forceps are indicated for electrosurgical coagulation, mechanical cutting, and grasping of tissue during the performance of laparoscopic and open general surgical procedures when used in conjunction with the general purpose ESG-400 workstation. The device is a single use, sterile accessory, to be used in

conjunction with the bipolar outputs of the Olympus workstation with PK software (ESG-400).

The proposed device is a modification of the Gyrus HALO PKS Cutting Forceps and includes an improved handle and improved jaw performance. The device handle has been redesigned with internal changes to improve ease of use. The jaws are identical as those found on the predicate Gyrus HALO PKS Cutting Forceps except that coatings have been added, and a mechanical bridge has been added inside the shaft.

Technological Characteristics

The Gyrus ACMI PK Cutting Forceps is a single use, sterile accessory for use with the ESG-400 Generator with updated PK software only, and is intended to provide the same performance as the predicate Gyrus HALO PKS Cutting Forceps. The modified device and the currently marketed device share the same intended use and the same operating principle, similar patient contacting materials, and the same processes of packaging and sterilization. Other than the coating, the distal jaws are identical as those found on the predicate Gyrus HALO PKS Cutting Forceps. The device may be activated via the handpiece coagulation switch or footswitch.

Material

The device uses similar patient-contacting materials that are utilized in the predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI.

The patient contacting items are classified in accordance with ISO 10993-1, as an external communicating, tissue/bone/dentin device for limited exposure (<24hrs.). ISO10993-1 and FDA Blue Book memo #G95-1 guidelines recommend that these direct patient contact parts have supporting data for cytotoxicity, sensitization and irritation. Full biocompatibility testing to ISO10993-1 for the device category was completed and is available for patient contacting materials.

The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogen Testing

Based on the material assessment, patient contacting materials were tested in accordance with ISO 10993-1, and results are considered passing.

Intended Use / Indications for Use

The PK Cutting Forceps are indicated for electrosurgical coagulation, mechanical cutting, and grasping of tissue during the performance of laparoscopic and open general surgical procedures when used in conjunction with the general purpose ESG-400 workstation.

Compliance to Standards

The design of the device complies with the following standards:

For pro-code GEI - FDA Recognized Consensus Standards: IEC 60601-2-2

Additional standards:
IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18
ISO 10993-1, 5, 7, 10, Biological Evaluation of Medical Devices
ISO 14971, Risk Analysis
ISO 15223-1:2012, Medical Devices - Symbols to be used
ISO 11135:2014, Sterilization of Health Care Products, EO Validation
ISO 11138: 2006, Sterilization of health care products: Biological Indicators
ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices
ISO 11607-2:2006, Packaging for Terminally Sterilized Medical Devices
ISO 11737-1:2006, Sterilization of Medical Devices – Microbiological Methods
ISO 11737-2:2009, Sterilization of Medical Devices – Microbiological Methods

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971. The design verification tests were identified and performed as a result of risk analysis assessment.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The device complies with the applicable clauses of IEC 60601-1, IEC 60601-2-2, and IEC 60601-2-18 standards for safety, and the IEC 60601-1-2 standard for EMC.

Summary of Sterilization and Shelf Life Discussion

The device is provided sterile for single-use. They are sterilized using Ethylene Oxide, using a cycle validated in accordance with ISO 11135 to provide a sterility assurance level of 10^{-6}.

The Shelf Life period for the device was determined through an analysis of the shelf-life stability of the materials used in the design of the device, as well as an analysis of the packaging materials and processes used with other Gyrus ACMI devices. Accelerated shelf-life studies were conducted to support an initial one year shelf life, with real time testing in process to confirm an initial one year expiration date. Additional studies (accelerated and real time) are planned to support a three–year expiration date in the future.

Summary of Performance Testing

Performance tests were executed to ensure that the device functions as intended and meets design specifications.

Evidence of safety and effectiveness was obtained from two primary areas:

1) non-clinical (electrical, mechanical, functional, stability) performance testing
2) preclinical (bench, ex-vivo tissue) evaluations and testing

Non-clinical: Basic safety and performance testing was performed in accordance with IEC 60601-1 and IEC 60601-2-2. In addition, verification and comparison bench studies were conducted to evaluate the mechanical and functional performance. Testing included: system testing, torque strength, endurance, force testing, reliability, ship testing, baseline performance testing, age testing, environmental conditioning, durability, dimensional verification, ergonomics, system compatibility, grasping, thermal margin, cutting, rotation, coagulation, and basic functionality.

Stability: Samples were subjected to accelerated aging to confirm that the device maintains functionality and continues to meet specifications over time. The results of the accelerated age testing demonstrate that the device will be stable for the stated shelf-life. In addition, real time age testing will be carried out to confirm the results of the accelerated age testing. Samples were also subjected to environmental conditioning and ship testing.

Preclinical: Evidence obtained from preclinical bench tissue (ex vivo) demonstrates that the device performs substantially equivalent to the predicate devices in relevant aspects associated with usability, cutting, coagulation, and tissue grasping. For bench testing, the selected tissue medium was confirmed to be appropriate for testing based on clinical experience with the predicate.

Bench tissue – evaluated ex vivo using bovine and porcine tissue:

- Thermal margin
- Visual comparison of coagulation

Testing demonstrated that the device performs as well as or better than the predicate device. Non-clinical bench testing and preclinical performance testing shows that the

device performance is substantially equivalent to the predicate, and that the modifications raise no new issues of safety and effectiveness.

No clinical testing was conducted. The use of Electrosurgical Cutting and Coagulation Devices has been documented in published literature and indicates safe and effective use for the target indications and expected patient populations.

Substantial Equivalence and Conclusion

The device utilizes similar bipolar electrosurgical energy to cut and coagulate tissue as that used in the predicate device.

The device uses similar patient-contacting materials in similar quantities that are utilized in the predicate device, as well as other legally marketed devices manufactured by Gyrus ACMI and others.

The performance of the device was compared against the known performance characteristics of the predicate device. Testing demonstrated that the performance requirements were met, and that the PK Cutting Forceps exhibited comparable performance characteristics to the predicates.

In summary, the PK Cutting Forceps is substantially equivalent to the predicate device and presents no new questions of safety or efficacy.