June 11, 2018

GRI Medical and Electronic Technology Co., Ltd.
% Sharon Marrow
Consultant
Sharon Marrow
2907 Cherry Branch Drive
Knoxville, TN 37948

Re: K172835
Trade/Device Name: GRI-Alleset Veress Needle
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: April 13, 2018
Received: May 10, 2018

Dear Sharon Marrow:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172835

Device Name
GRI-Alleset Veress Needle

Indications for Use *(Describe)*

The GRI-Alleset Veress Needle is a disposable, single-use, sterile device intended to be used in minimally-invasive abdominal procedures for the establishment of pneumoperitoneum.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

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510(K) SUMMARY

1. 510(k) Summary

Date Prepared: June 8, 2018

1.1 Applicant: Owner and Official Correspondent

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1.1. Device Trade Name: Trade/Proprietary Name

GRI-Alleset Veress Needle

Common or Usual Name:	Veress Needle
Regulation Name:	Laparoscopic insufflator
Regulation Number:	21 CFR 884.1730
Class:	II
Product Code:	HIF (insufflator, laparoscopic)

1.2. Predicate Device:

Device Name:	Endopath Ultra Veress Needle
510(k) Number:	K983925
Manufacturer:	Ethicon Endosurgery, Inc.

The predicate device has not been subject to a design related recall.

1.3. Description of the Device

The GRI-Alleset Veress Needle is a disposable, single-use, sterile surgical instrument used during minimally invasive surgery for the establishment of peritoneum of the abdominal cavity prior to abdominal surgery. The device is comprised of a 14 gauge stainless steel needle (120mm and 150mm in length) which is attached to a plastic handle that contains a stopcock with a luer lock

connector. The spring-loaded, blunt stylet extends beyond the needle tip and retracts as the needle is pushed through the abdominal tissue; it automatically advances forward once the peritoneum is penetrated. A red safety indicator, attached to the proximal end of the stylet, is exposed above the handle as an indication of an exposed needle tip. The device is provided sterile via ethylene oxide.

1.4. Indications for Use

The GRI-Alleset Veress Needle is a disposable, single-use, sterile device intended to be used in minimally-invasive abdominal procedures for the establishment of pneumoperitoneum.

1.5. Comparison to the Predicate Device

The table below provides an overview of the comparison of the new device to the predicate device. As noted in the table below, the subject and predicate device have the same intended use. There are also differences in technological characteristics between the subject and predicate device; however, these differences do not raise different questions of safety or effectiveness.

Element of Comparison		**Subject Device**	**Predicate Device**
General	Manufacturer	GRI	Ethicon (K983925)
	Trade Name	Veress Needle	Ultra Veress Needle
	Class	II	II
	Regulation Name	Laparoscopic insufflator	Laparoscopic insufflator
	Product Code	HIF	HIF, FHP
Intended Use	Intended User	Surgeons in operating room	Surgeons in operating room
	Intended Use	The Veress Needle has application in minimally invasive abdominal procedures for the establishment of pneumoperitoneum.	The ENDOPATH Ultra Veress Insufflation Needle has application in gynecologic laparoscopy and other minimally invasive abdominal procedures for establishment of pneumoperitoneum.

Element of Comparison		Subject Device	Predicate Device
Technological Characteristics	Device Description	14 gauge, 120mm and 150mm, two way valve with luer lock connector, red safety indicator	14 gauge, 120mm and 150mm, optional stop cock with luer lock connector, red safety indicator
	Materials/Composition	Stainless steel, ABS	Stainless Steel, ABS
	Sterility	Provided Sterile via EtO; Single-Use Disposable	Provided Sterile via Gamma Radiation; Single-Use Disposable
	Length	120mm, 150mm	120mm
	Diameter	2.1mm (14 gauge)	14 gauge
	Luer Lock Connector	Yes	Yes
	Spring Loaded	Yes	Yes
	Indicator for when in peritoneal cavity	Yes (red indicator)	Yes (red ball)
	Sterile Packaging	Tyvek to PET peel pouch	Tyvek to poly peel pouch
	Design Differences	Handle design (shape)	Handle Design (shape); indicator for Ultra Veress Needle is red ball, has optional luer connector

1.6. Summary of non-clinical tests submitted

Cytotoxicity, irritation and sensitization testing were conducted according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-12:2012. The results demonstrate that the subject device is biocompatible.

Sterilization validation was performed according to ISO 11135-1:2014. Ethylene Oxide residuals were evaluated according to ISO 10993-7:2008 and are acceptable.

Mechanical bench testing, including assessments of gas flow, leakage, max puncture force, rotational valve operation, stylet alignment, stylet strength, connector fitting, and audible rate, were conducted in comparison with the predicate, Ethicon Endopath Ultra Veress Needle. All

performance tests show acceptable results and demonstrate that the GRI-Alleset Veress Needle meets its specifications.

Shelf life testing demonstrates that the subject device maintains its functional performance and its packaging maintains device sterility over the duration of the proposed shelf life.

1.7. Conclusion of the tests

The results of performance testing demonstrate that the GRI-Alleset Veress Needle is substantially equivalent to the Ethicon Endopath Ultra Veress Needle.