December 13, 2018

Mariner Endosurgery Inc.
% Joel Ironstone
President
Ironstone Product Development Inc.
Suite 222, 276 Carlaw Ave
Toronto, M4M 3L1 Canada

Re: K182434
Trade/Device Name: LaparoGuard
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 31, 2018
Received: September 6, 2018

Dear Joel Ironstone:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2018.12.13 08:54:03 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182434

Device Name
LaparoGuard

Indications for Use *(Describe)*
LaparoGuard is indicated for use with compatible laparoscopic devices. LaparoGuard can be used in general laparoscopy wherever a laparoscope is indicated for use.

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.

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510(k) SUMMARY

Mariner Endosurgery's LaparoGuard

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Mariner Endosurgery Inc.
Suite 305A, 175 Longwood Road South
Hamilton, ON, Canada
L8P 0A1

Phone: +1 905-921-8755
Contact Person: Mitchell Wilson

Date Prepared: August 31, 2018

Name of Device

LaparoGuard

Device Classification and Product Code

Endoscope and accessories, 21 CFR 876.1500, Class II, GCJ

Predicate Devices

Stryker Endoscopy's SDC3 HD Information Management System (K121893)

Indications for Use

LaparoGuard is indicated for use with compatible laparoscopic devices. LaparoGuard can be used in general laparoscopy wherever a laparoscope is indicated for use.

Device Description

LaparoGuard allows surgeons to virtually annotate a safe anatomical volume ("safe zone") inside the body cavity of a patient during a laparoscopic surgery. A compatible laparoscope, such as the ConMed IM3300 (K031098), captures video feed that is processed by LaparoGuard, which tracks surgical instruments and the safe zone boundaries to display a real-time overlay on a compatible laparoscope monitor, such as the Stryker Vision Elect 21" (K081995). Surgical teams receive visual and auditory notifications throughout the procedure whenever a tracked instrument has exited the safe zone. LaparoGuard consists of the components listed in the table below:

Table 1 - LaparoGuard Components

LaparoGuard Component	Part Number	Single Use / Reusable
Trackers	Type #1: C00261	Single Use
	Type #2: C00262	Single Use
	Type #3: C00263	Single Use
	Type #4: C00264	Single Use
	Type #5: C00265	Single Use
Probe	C00234	Single Use
Calibrator	C00233	Single Use
NDI Camera	M00034	Reusable
Controlling PC	X00021	Reusable
Power Supply	X00026	Reusable
Video Capture Box	X00022	Reusable
DVI-D Bypass Cable	X00023	Reusable
Support Cart	X00019	Reusable

Non-Clinical Testing

Non-Clinical testing was conducted on the LaparoGuard system including:

- Characterization of system accuracy using an accuracy measurement phantom
- Characterization of laparoscopic image fidelity
- Characterization of system display latency
- Software verification and validation for each requirement
- System integration testing using anatomical phantoms

Standards Compliance

LaparoGuard has been tested to be in compliance with the following FDA recognized standards:

- Electrical safety testing per IEC 60601-1:2005 (Third Edition) + C1:2006 + C2:2007 + A1:2012
- EMC per IEC 60601-1-2:2014 (4th Edition).
- Positional accuracy of computer assisted surgical systems, as per ASTM F2554-10
- Software validation per FDA's *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 11, 2005)

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern, as failures or latent design flaws are unlikely to cause any injury to the patient or operator.

Substantial Equivalence

LaparoGuard is substantially equivalent to Stryker Endoscopy's SDC3 HD Information Management System. LaparoGuard has the same intended use as the predicate device. The differences in technological characteristics do not raise new questions of safety or effectiveness. LaparoGuard has been tested to FDA-recognized standards to demonstrate its safety and effectiveness. Thus, LaparoGuard is substantially equivalent to the predicate device. A summary of the substantial equivalence comparison is provided in the table below:

Table 2 - Substantial Equivalence Comparison Table

CHARACTERISTIC	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE
Device Name	LaparoGuard	SDC3 HD Information Management System	Explorer Liver --- Passive Tracking
Manufacturer	Mariner Endosurgery	Stryker Endoscopy	Pathfinder Therapeutics
510(k) Number	-	K121893	K101979
Regulatory Class	Class II	Class II	Class II
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 882.4560
Product Classification	GCJ	GCJ	OEW
Classification Name	Endoscope and accessories	Endoscope and accessories	Stereotaxic instrument
Intended Use	Adjunctive aid for the monitoring of compatible instruments during laparoscopic surgery	Adjunctive aid for the monitoring and control of compatible instruments during endoscopic, laparoscopic, or arthroscopic procedures. Additionally, has operating room documentation functionality and ability to export recorded video/images.	Adjunctive aid for monitoring of compatible instruments during open liver surgical procedures, along with image-guidance using preoperative, patient-specific MRI or CT medical images.
Indications for Use Statement	LaparoGuard device is indicated for use with compatible laparoscopic devices. LaparoGuard can be used in general laparoscopy wherever a laparoscope is indicated for use.	The Stryker SDC3 HD Information Management System (SDC3) is intended for use with compatible endoscopic and general surgery devices. SDC3 can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope, endoscope, or an arthroscope is indicated for use.	The Explorer™ Liver --- Passive Tracking device is indicated for open liver surgical procedures where image-guidance may be appropriate and where the patient can tolerate long apneic periods under general anesthesia.

CHARACTERISTIC	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE
		A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, anterior cruciate ligament reconstruction, knee arthroscopy, shoulder arthroscopy, small joint arthroscopy, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. SDC3 users are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.	
Environment	Surgical Suite	Surgical Suite	Surgical Suite
Users	General surgeons, gynecologists, plastic surgeons and urologists.	General surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.	General surgeons
Patient Population	Any patients undergoing laparoscopic procedures	Any patients undergoing endoscopic procedures	Patients undergoing open liver surgical procedures where image-guidance may be appropriate and who can tolerate long apneic periods under general anesthesia
Anatomical Sites	Abdomen	Whole Body (anywhere where an endoscope may be used)	Liver

CHARACTERISTIC	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE
Procedural Overview	Allows the surgeon to monitor the position of tracked compatible instruments relative to a virtual three-dimensional "safe zone" and target location established by the surgeon at the initiation of the procedure, using a tracked probe. Using a digital representation, tracked instruments are displayed relative to each other and to the safe zone.	Allows the surgeon to monitor and control the status/settings of any compatible instrument attached to it.	Allows the surgeon to monitor the position of tracked compatible instruments relative to tumors and surrounding anatomic structures, based on preoperative, patient-specific MRI or CT medical images. Using a digital representation, tracked instruments are displayed relative to each other and to the surrounding anatomy.
Electrical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1	Compliance to IEC 60601-1
Energy delivered or controlled	None delivered to patient	None directly delivered to patient; however, device can control the delivery of energy from compatible instruments	Some laser energy delivered to patient through the use of a Laser Range Scanner component
Notifications	Provide visual and auditory notification when tracked instruments exit the surgeon-defined “safe zone”	Provides visual and auditory notification of surgeon-defined “time outs” during which all compatible instruments are turned off	N/A
Display of Monitored Instruments	Both integrated into laparoscopic camera video feed output and digitally represented on a standalone monitor	Integrated into endoscopic camera video feed output	Digitally represented on a standalone monitor
Tracking Technology	Polaris Spectra optical position sensor	N/A	Polaris Spectra or Vicra optical position sensors
Method of Optical Tracking	Retroreflective passively tracked spheres (NDI Passive Spheres - K033621) incorporated onto tracked adapters	N/A	Retroreflective passively tracked spheres (NDI Passive Spheres - K033621) incorporated onto tracked adapters
Number of Passive Spheres per Tracked Adapter	Four	N/A	Four
Compatible Instruments	Rigid instruments only	Powered instruments	Rigid instruments only
Number of Compatible Instruments Monitored or Controlled at a Time	Five	Five	Five
Connection to Compatible Instruments	Passively optically tracked adapters	Wired connection	Passively optically tracked adapters

CHARACTERISTIC	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE
Compatible Instrument Calibration	Supports calibration of an instrument's tip position and orientation simultaneously using a calibration fixture	N/A	Supports calibration of an instruments's tip position and orientation simultaneously using a calibration fixture
Method for User Indication of Targeted Anatomical Structures	Tracked probe	N/A	Tracked Probe
Patient Contacting Components	Tracked probe	No patient contacting components	Tracked probe and tracked abdominal reference
Biocompatibility	Biocompatible stainless steel	N/A	Biocompatible stainless steel and other materials tested per ISO 10993-1
Sterility	Manufacturer-sterilized, single use only	N/A	End-user sterilized, reusable

Conclusions

LaparoGuard has the same intended use and indications for use as its predicate device. Differences in technological characteristics do not raise new questions of safety or effectiveness. Therefore, LaparoGuard is substantially equivalent to its predicate.