January 23, 2023

Covidien, llc
Miranda Miles
Regulatory Affairs Specialist
5920 Longbow Dr.
Boulder, Colorado 80301

Re: K223158
Trade/Device Name: LigaSure™ XP Maryland Jaw Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 21, 2022
Received: December 27, 2022

Dear Miranda Miles:

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/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 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Jessica Carr -S

for Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223158

Device Name
LigaSure™ XP Maryland Jaw Sealer/Divider

Indications for Use *(Describe)*
The LigaSure XP Maryland Jaw Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, thick tissue (tissue bundles), and lymphatics is desired. The LigaSure XP Maryland Jaw Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as colorectal, bariatric, urologic, vascular, thoracic, and gynecologic. These may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, and so forth.

The LigaSure XP Maryland Jaw Sealer/Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure XP Maryland Jaw Sealer/Divider for these procedures.

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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COVIDIEN

510(k) Summary

Date summary prepared: January 19, 2023

510(k) Submitter/Holder

Covidien llc
5920 Longbow Drive
Boulder, CO 80301

Contact

Miranda Miles, Regulatory Affairs Specialist
Telephone: 303-530-6205
Email: miranda.r.miles@medtronic.com

Proposed Device

Trade Name:	LigaSure™ XP Maryland Jaw Sealer/Divider
Catalog Numbers:	LXMJ23S, LXMJ37S, LXMJ44S, LXMJ23L, LXMJ37L, LXMJ44L
Common Name:	Bipolar Vessel Sealing Device
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI)

Predicate Devices

The primary predicate device is the LigaSure™ Maryland Jaw Sealer/Divider, One-Step Sealing, Nano-Coated cleared under K170869 and the secondary predicate device is the LigaSure™ Blunt Tip Sealer/Divider, Nano-Coated cleared under K162941.

Primary

Trade Name:	LigaSure™ Maryland Jaw Sealer/Divider, One-Step Sealing, Nano-Coated
Catalog Numbers:	LF1923, LF1937, LF1944
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI)
510(k) Number:	K170869 cleared April 21, 2017

Secondary

Trade Name:	LigaSure™ Blunt Tip Sealer/Divider, Nano-Coated
Catalog Numbers:	LF1823, LF1837, LF1844
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI)
510(k) Number:	K162941 cleared November 14, 2016

Device Description

The proposed LigaSure™ XP Maryland Jaw Sealer/Divider is a sterile, single-use bipolar vessel sealer. It is labeled as prescription use only. The device connects to the Valleylab™ FT10 Electrosurgical Platform generator for tissue ligation. Energy is applied to tissue interposed between the nano-coated Maryland-style jaws creating a ligation. The jaws contain an independent cutting blade for division of tissue. A distinctive characteristic is the new continuous rotation capability of the jaws and shaft. The shaft is a common 5 mm diameter available in three lengths (23 cm, 37 cm, 44 cm) for various general surgical procedures in both open and minimally invasive (laparoscopic) approaches. The instrument body is a pistol grip design which can be used by right or left-handed users to access the controls. The new device is offered with two handle body designs, One-Step Sealing (LXMJ23S, LXMJ37S, LXMJ44S) or Latching Handle (LXMJ23L, LXMJ37L, LXMJ44).

Indications for Use

The LigaSure XP Maryland Jaw Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, thick tissue (tissue bundles), and lymphatics is desired. The LigaSure XP Maryland Jaw Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as colorectal, bariatric, urologic, vascular, thoracic, and gynecologic. These may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, and so forth.

The LigaSure XP Maryland Jaw Sealer/Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure XP Maryland Jaw Sealer/Divider for these procedures.

Comparison of Technological Characteristics with the Predicate Devices

The LigaSure™ XP Maryland Jaw Sealer/Divider has the same intended use compared to the predicates with different indications and some different technological characteristics. A summary comparison is provided in the table below.

Characteristic	**Proposed Device:** LigaSure™ XP Maryland Jaw, Sealer/Divider, Nano-Coated, One-Step Sealing/ Latching Handle	**Primary Predicate Device:** LigaSure™ Maryland Jaw Sealer/Divider, Nano-Coated, One-Step Sealing (K170869)	**Secondary Predicate Device:** LigaSure™ Blunt Tip Sealer/Divider, Nano-Coated, (K162941)	**Results** (compared to predicates)
Indications for Use	The LigaSure XP Maryland Jaw Sealer/Divider is a bipolar electrosurgical instrument intended for	The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally	The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally	The proposed indications for use statement includes colorectal and bariatric specialties, clarifies the

	use in minimally invasive or open surgical procedures where ligation and division of vessels, thick tissue (tissue bundles), and lymphatics is desired. The LigaSure XP Maryland Jaw Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as colorectal, bariatric, urologic, vascular, thoracic, and gynecologic. These may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, and so forth. The LigaSure XP Maryland Jaw Sealer/Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure XP Maryland Jaw Sealer/Divider for these procedures.	invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. These may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. The LigaSure System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure™ system for these procedures.	invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, such procedures as Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. The LigaSure System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure™ system for these procedures.	term tissue bundles with the term thick tissue and replaced ‘etc.’ with ‘and so forth’. Differences do not change the intended use of the device and do not affect safety and effectiveness as demonstrated through performance testing.
Sterile	Yes	Yes	Yes	Same
Product Packaging	Single sterile barrier	Single sterile barrier	Single sterile barrier	Same
Instrument Design	Pistol Grip	Pistol Grip	Pistol Grip	Same
Lever Latching Mechanism	LXMJxxS: No LXMJxxL: Yes	No	Yes	Same; Same technological characteristic.
Energy Activation Mechanisms	Button or footswitch	Button or footswitch	Button or footswitch	Same

Shaft/Jaws Rotation Distance	Continuous 360°	350°	180°	The proposed device can rotate continuously 360° in both directions. Differences do not affect the safety and effectiveness and do not raise different questions of safety and effectiveness as demonstrated through performance testing.
Jaw Type	Unilateral	Unilateral	Bilateral	Same; Same technological characteristic.
Jaw Shape	Curved	Curved	Blunt	Same; Same technological characteristic.
Electrical Characteristics				
Energy Type	bipolar electrosurgical	bipolar electrosurgical	bipolar electrosurgical	Same
Compatible Energy Platform	VLFT10GEN (K191601)	VLFT10GEN (K191601) VLLS10GEN (K143654) FORCETRIAD (K110268)	VLFT10GEN (K191601) VLLS10GEN (K143654) FORCETRIAD (K110268)	Same; VLFT10GEN is compatible with the predicates.
Operating Amperage (Maximum)	VLFT10GEN: 5.5 A	VLFT10GEN: 5.5 A VLLS10GEN: 6.1 A FORCETRIAD: 6.1 A	VLFT10GEN: 5.5 A VLLS10GEN: 6.1 A FORCETRIAD: 6.1 A	Same; VLFT10GEN is compatible with the predicates.
Operating Voltage (Maximum)	VLFT10GEN: 244 Vpk @ 434 kHz	VLFT10GEN: 244 Vpk @ 434 kHz VLLS10GEN: 250 Vpk @ 400 kHz FORCETRIAD: 288 Vpk @ 472 kHz	VLFT10GEN: 244 Vpk @ 434 kHz VLLS10GEN: 250 Vpk @ 400 kHz FORCETRIAD: 288 Vpk @ 472 kHz	Same; VLFT10GEN is compatible with the predicates.
Direct Tissue Contacting Materials				
Patient Contacting Materials Biocompatible	Yes	Yes	Yes	Same
Jaw Coating	Yes	Yes	Yes	Same
Shaft Material	Stainless steel	Stainless steel with black heat shrink wrap	Stainless steel with black heat shrink wrap	Removal of heat shrink does not affect the safety and effectiveness and does not raise different questions of safety and effectiveness as demonstrated through performance testing.

Performance Testing

The following testing performance data are provided in support of the substantial equivalence determination of the LigaSure™ XP Maryland Jaw Sealer/Divider.

Sterilization and Shelf Life

The LigaSure™ XP Maryland Jaw Sealer/Divider met the acceptance criteria for sterilization by ethylene oxide (EO) in accordance with the applicable validation standards ISO 11135, ISO 11737-1, ISO 11737-2, and ISO 10993-7. In addition, the LigaSure™ XP Maryland Jaw Sealer/Divider packaging and product integrity were found to be acceptable for the five-year shelf life in accordance with the applicable packaging standards ISO 11607-1, ISO 11607-2, ASTM D4169 and ASTM F1980.

Biocompatibility

The LigaSure™ XP Maryland Jaw Sealer/Divider met the requirements of biocompatibility standard ISO 10993-1 for the following endpoints: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, and material-mediated pyrogenicity.

Software

The LigaSure™ XP Maryland Jaw Sealer/Divider does not contain software.

Electromagnetic Compatibility and Electrical Safety

The LigaSure™ XP Maryland Jaw Sealer/Divider met the applicable clauses of electromagnetic compatibility and electrical safety verification standards IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, and IEC 60601-2-18.

Performance Testing – Bench

The LigaSure™ XP Maryland Jaw Sealer/Divider bench testing studies met the predetermined device requirements (acceptance criteria) for mechanical/functional performance, visual inspection, device reliability, ex vivo vessel sealing/burst and ex vivo lymphatic sealing/burst testing.

Performance Testing – Animal

The LigaSure™ XP Maryland Jaw Sealer/Divider met all predetermined device requirements (acceptance criteria) for in vivo acute hemostasis, acute thermal spread and chronic hemostasis tissue testing.

Performance Testing – Clinical

Clinical literature studies were evaluated to further support the safety and effectiveness use of the proposed LigaSure™ XP Maryland Jaw Sealer/Divider indications for use.

Conclusion

The proposed LigaSure™ XP Maryland Jaw Sealer/Divider device family is substantially equivalent to the predicate device families LigaSure™ Maryland Jaw Sealer/Divider, One-Step Sealing, Nano-Coated and LigaSure™ Blunt Tip Sealer/Divider, Nano-Coated.