510(k) SUMMARY

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Name of Device:

Trade/Proprietary Name: Reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider (LF4418)

Common Name: Bipolar Electrosurgical Instrument

Classification Name: Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed (21 CFR§878.4400, Product Code NUJ, Class II)

Predicate and Reference Devices:

	Model Number	**510(k) Number**	**510(k) Title**	**Original Manufacturer**
Predicate Device	LF4318	K141153	LigaSure Tissue Sealer/Dividers (Indications for Use)	Covidien
		K123444	LigaSure Impact Curved, Large Jaw, Open Sealer/Divider	Covidien
Reference Device	LF4318	K150538	Reprocessed LigaSure Impact Curved, Large Jaw, Open Sealer/Divider	Stryker Sustainability Solutions
Reference Device	LF4418	K162047	LigaSure Impact Curved, Large Jaw, Open Sealer/Divider, Nano-coated	Covidien

Device Description:

The Reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider (LF4418) is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LF4418 is

designed for use with Covidien electrosurgical generators that include vessel sealing capability. The LigaSure Sealer/Divider can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins) up to and including 7mm.

The instrument creates a seal by application of radiofrequency (RF) electrosurgical energy to vascular structures (vessels and lymphatics) or tissue bundles interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

The following controls are located on the instrument handle:

- A lever for opening and closing the instrument jaws. The mechanism incorporates a latch to hold the jaws in the closed position during vessel sealing and cutting.
- An activation button for generator power to initiate vessel sealing.
- A trigger for actuating the cutter.
- A knob to rotate the instrument jaws.

All controls can be operated with either the right or left hand. Vessel sealing can be initiated using the activation button or utilizing a footswitch connected to the generator.

The instrument attaches to the compatible electrosurgical generator via a cord with a cable connector that identifies the instrument type to the generator.

For the LF4418, the Original Manufacturer applies a non-stick coating to the jaws of the device to reduce tissue sticking. When reprocessing the LF4418, Stryker Sustainability Solutions will not apply a non-stick coating to the jaws of the device.

The scope of this submission only includes the reprocessed Covidien™ sealer/divider device and not the ForceTriad™ Energy Platform or Valleylab™ FT10 Energy Platform that are used to power the device or the footswitch that connects to the generator. Stryker Sustainability Solutions does not reprocess or market the generator or footswitch.

Intended Use:

The Reprocessed LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The Reprocessed LigaSure Sealer/Divider can be used on vessels (arteries, veins, pulmonary arteries, pulmonary 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, 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.

Summary of Technological Characteristics:

The design, materials, and intended use of Reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider are equivalent to the predicate device. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. The differences between the predicate

device and the reprocessed device include the replacement of some components with new components. The replacement components are manufactured to the same specifications and from equivalent materials as the components they are replacing. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization Validation
- Functional Performance Tests
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Packaging Validation

The functional performance testing involved electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2, and verification/comparative testing (to the predicate device). The bench testing involved evaluation of the device's performance and ability to seal and divide vessels up to 7 mm, including: burst pressure, maximum jaw temperature, device functionality, device reliability, and generator compatibility.

Additionally, preclinical laboratory evaluations in an animal model were performed, which included acute and chronic survival studies. The studies were done to evaluate thermal spread and the ability to achieve hemostasis of vessels of the reprocessed device. The results of the evaluations demonstrate that the Reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider effectively cut and coagulated vessels up to and including 7mm in diameter.

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

Conclusion:

Stryker Sustainability Solutions concludes that the Reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider is at least as safe and effective as the predicate device as described herein.