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Stryker's Sustainability Solutions Reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider (LF1212A) and Remanufactured LigaSure Exact Dissector, Without Nano-Coating (LF2019):

A Pre-Clinical Comparison to Original Manufacturer LigaSure Curved, Small Jaw, Open Sealer/Divider and LigaSure Exact Dissector, Nano-coated

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Study summary

Stryker's Sustainability Solutions (SSS) Reprocessed LF1212A and Remanufactured LF2019 devices were compared to the original manufacturer (OM) devices and **found to perform as well as OM devices for seal integrity (hemostasis) in an acute study.** This was determined by assessments at one and ten minute marks after vessel sealings were performed. **Additionally, a chronic, 21-day animal survival study was performed, which demonstrated effective long-term seal quality of the reprocessed/remanufactured devices (pertains to both LF1212A and LF2019).** The pathological gross assessment of the surviving animals demonstrated healed vascular seal sites with acceptable long-term seal quality and no indication of recent or active bleeding. In addition, there were no hemostatic complications or evidence of thermal injury to adjacent tissue attributed to use of the reprocessed/remanufactured devices for both models (LF1212A and LF2019).

Background

Advanced directed energy vascular sealing instruments have become essential with the proliferation of endoscopic procedures, as well as general surgical procedures. These devices are of vital importance to providing hemostasis while sealing and dividing vessels. **With over two decades of reprocessing experience, Stryker's Sustainability Solutions business is the market-leading provider of reprocessing services for medical devices.** Reprocessing of single use medical devices must demonstrate substantial equivalence. "Substantial equivalence" to a legally marketed (predicate) device is demonstrated through Premarket Notification, or 510(k) clearance, in accordance with the Food and Drug Administration (FDA) Code of Federal Regulations (21CFR Part 807).[1] The remanufactured exact dissector followed the exact same regulatory pathway of demonstrating substantial equivalence to a legally marketed (predicate) device through Premarket Notification, or 510(k) clearance, in accordance with 21CFR Part 807). Vessel sealing is an important aspect to be measured to verify equivalence between the reprocessed/remanufactured and OM devices, which can be assessed in an acute animal study. FDA guidance for bipolar electrosurgical vessel sealers states that in order to assess the long-term seal quality and potential for injury to adjacent structures, a chronic animal study should evaluate device performance at a minimum of three (3) weeks post-procedure in at least five (5) animals.[2] As part of the verification and validation activities conducted to demonstrate substantial equivalence to the predicate, acute and chronic animal studies were designed and executed in a porcine model in accordance with the FDA guidance. The results of the seal integrity evaluation are outlined in the succeeding discussion.

Method

The preclinical studies consisted of American Preclinical Services (APS) approved protocols using a porcine model[3,4]. The anatomy and physiology of the porcine model provided a tissue response to electrosurgical instrumentation similar to that of human tissues. The surgeon and pathologist were blinded as to the device identification (OM vs. reprocessed/remanufactured) until after all scoring and gross evaluation were completed to eliminate bias.

The chronic, 21-day survival study was designed to assess long-term seal quality and potential for injury to adjacent structures. Multiple vessel types and diameters per animal were sealed using reprocessed/ remanufactured and OM LigaSure LF1212A and LF2019 devices. For the chronic, 21-day survival study, a total of six (6) subject animals (where one reprocessed device was used for each subject), plus one (1) control animal (OM device was used) underwent a splenectomy, unilateral nephrectomy and bilateral oophorectomy, and all vessels associated with the organs were sealed with a LigaSure LF1212A device (six reprocessed plus one OM device). A gross evaluation was performed at day 21 to assess hemostasis of the sealed vessels and any collateral tissue changes, as appropriate. Similarly, the same amount of devices and animals (different set of animals than used for LF1212A devices) were used for the LF2019 devices.

The acute animal study was designed to compare four (4) subject animals and three (3) control animals, where a total of seven (7) porcine test systems were used for the LF1212A model study. For the LF2019 model study three (3) subject animals and three (3) control animals for a total of six (6) porcine test systems were used. One reprocessed/remanufactured device was used for each subject animal and one OM device was used for each control animal. Each animal underwent procedures to seal multiple vessels of different sizes and with various physiological functions as indicated in Table 1.

Vessel type	Vessel identification
A/V bundle	Ovarian pedicle, short gastric, splenic, uterine bundle
Artery	Carotid, gastric splenic, large intestinal, rectal, renal, small mesenteric, splenic
Vein	Gastric splenic, internal jugular, large intestinal, rectal, renal, small mesenteric, splenic

Table 1. OM LF1212A blade vs. reprocessed LF1212A blade under magnification

For tissue sealing (hemostasis) during the acute study, a scoring code was used for visual confirmation of maintained tissue sealing after one minute and ten minutes ‡. Assessments were made by the surgeons during the vessel sealing procedures. Descriptive statistics comparison was done to compare the median of the scoring assessments taken from all the reprocessed/remanufactured devices compared to the median of the scoring assessments for all the OM devices used during the procedures. The raw data and detailed statistical analysis are contained in the report on file.[3,4]

Results

The LigaSure LF1212A and LF2019 devices are indicated for sealing vessels (arteries and veins) up to and including seven (7) mm. The intended use for the LigaSure LF1212A and LF2019 devices are vessels (arteries and veins) up to and including seven (7) mm. Table 2 and Table 3 below gives the summary of all the vessels sealed during the acute study for the LF1212A and LF2019 devices.

Vessel size	LF1212A test arteries sealed	LF1212A test veins sealed	LF1212A test AV bundles sealed	LF1212A OEM arteries sealed	LF1212A OEM veins sealed	LF1212A OEM AV bundles sealed
1mm	0	2	6	2	0	8
2mm	8	2	4	1	2	6
3mm	1	10	7	7	6	6
4mm	4	3	10	4	5	3
5mm	10	7	5	6	2	6
6mm	8	3	3	5	3	3
7mm	3	2	4	4	2	6

Table 2. LF1212A sealed vessels size distributions (acute study)

Vessel size	LF2019 test arteries sealed	LF2019 test veins sealed	LF2019 test AV bundles sealed	LF2019 OEM arteries sealed	LF2019 OEM veins sealed	LF2019 OEM AV bundles sealed
1mm	0	4	5	1	4	1
2mm	4	1	7	6	3	7
3mm	5	4	8	5	7	8
4mm	9	6	9	4	4	2
5mm	6	3	9	14	4	9
6mm	3	2	0	2	7	6
7mm	1	1	2	0	1	2

Table 3. LF2019 sealed vessels size distributions (acute study)

Seal integrity

For seal integrity one hundred and three (103) data points were obtained for reprocessed LF1212A devices, and eighty-seven (87) data points for OM LF1212A devices. Eighty-nine (89) data points were obtained for remanufactured LF2019 devices, and ninety-seven (97) data points for OM LF2019 devices. Seal integrity data points were made up of seal integrity (any leaking) assessments made at the one minute and ten minute mark after sealing the vessel ‡. **There was no statistical difference between the reprocessed/remanufactured and OM data groups. The average seal integrity rating for both reprocessed/remanufactured and OM was 1.00, indicating adequate seal at tissue site with no leakage of blood (complete hemostasis) as evaluated by the surgeon, and according to the established ranking scale. At all seal sites the vessel was closed or sealed and there was no evidence of hemorrhage, vascular leakage, or fibrin deposition on the ends. Additionally, there was no loss of vascular structure such as arterial dissection or arterial/venous medial thinning observed in any site (OM or reprocessed/remanufactured).** All statistical analysis can be found in SSS internal reports.[3,4]

Chronic study

At 21-day necropsy, the pathological gross assessment of the surviving animals demonstrated healed vascular seal sites with acceptable longterm seal quality and no indication of recent or active bleeding. **In addition, there were no hemostatic complications or evidence of thermal injury to adjacent tissue attributed to use of the reprocessed/remanufactured device. The chronic study provides further assurance that the reprocessed/remanufactured LigaSure devices (LF1212A and LF2019) will perform as intended to provide acceptable long-term seal quality and is safe for human use.**

Conclusion

The reprocessed/remanufactured devices that compared to brand new models (OM LF1212A and OM LF2019) during the acute animal study, in addition to the chronic animal study, demonstrated long-term seal quality was achieved for reprocessed/remanufactured devices. The data analyzed for tissue sealing showed statistical equivalence between the reprocessed/remanufactured and OM devices. This demonstrates that the reprocessed/remanufactured devices performed comparably to the OM devices with regards to device performance in the acute and chronic in vivo porcine model. Data from these acute and chronic in vivo studies were provided as part of an FDA 510(k) pre-market notification.

‡ The four-tiered scoring code used for the visual assessments were as follows:

Evaluation	Scoring code
Seal integrity	1- Seal at treatment site, no blood or lymph leakage
	2- Seal at treatment site, with slight oozing of blood or lymph that stops within 1 minute ± 15 seconds
	3- Partial sealing, with brisk blood or lymph leakage present that requires intervention
	4- Incomplete sealing, with uncontrolled blood or lymph leakage requiring intervention

References

1. 21 CFR Part 807, Subpart E, Premarket Notification Procedures.
2. Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery, Guidance for Industry and Food and Drug Administration Staff, Issued August 15, 2016.
3. Reports on file. TR20956 Engineering Study Report Design Validation Study (Acute, Chronic, and Lymphatic GLP) for LigaSure Small Jaw (LF1212A); and TR21208 Statistical Analysis for Acute Animal Study on Reprocessed LigaSure Small Jaw, LF1212A.
4. Reports on file. TR21190 Engineering Study Report Design Validation Study (Acute, Chronic, and Lymphatic GLP) for Ligasure Exact Dissector (LF2019); and TR21209 Statistical Analysis for Acute Animal Study on Remanufactured LigaSure Exact Dissector (LF2019).