DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K180451

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

Indications for Use *(Describe)*
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.

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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Reprocessed Single-Use Device Model Included in Clearance

Device Model	Device Name	Original Manufacturer
LF4418	LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider	Covidien