Value Analysis Brief

LigaSure™ Maryland Jaw
Open / Laparoscopic Sealer / Divider
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Introduction
Since 1967, Covidien Energy has been a catalyst for innovation and a standard bearer for quality.

Connected in purpose with surgeons, we are pioneers that apply passion, ingenuity and hands-on expertise to consistently advance energy solutions.

We empower surgeons and administrators to confidently deliver their highest level of performance to enhance patient outcomes with solutions for optimal surgical results.
What Sets Covidien Apart?

• Through mission-critical engagement, we listen and respond to patient, surgeon and hospital needs. Our efforts are consistently directed towards the same goals as yours.

• Surgery has to be 100% every time. We care about our work and hold ourselves accountable to deliver excellence. No almost, no pretty good, no apologies.

• We always see the potential to accomplish more. As we look around the corner, we illuminate the future and leap ahead of our competitors.

• With so much at stake, we endeavor to embrace ever-greater challenges. Apply head, heart, hands and activate Covidien Energy, a formula for dynamic performance.

• As an industry leader focused on performance and results, our advanced-energy solutions bridge the modalities from traditional electro-surgery to ultrasonic and RF vessel sealing.
Covidien offers a comprehensive portfolio of energy solutions that address the full spectrum of clinical energy needs. We achieve this by working directly with healthcare professionals around the world to design and develop technologies that meet their needs in performance and value.

**ForceTriad™ Energy Platform**
The ForceTriad™ energy platform offers enhanced monopolar and bipolar energy and the next generation of LigaSure™ vessel sealing technology – all in one unit. It’s the industry’s only full-featured platform with remote software upgrade capabilities. Quality and compatibility of components is ensured when your electrosurgery system bears the Covidien name.

**LigaSure™ Technology**
Since its introduction to the market in 1998, LigaSure™ technology has set the industry standard for vessel sealing. The technology has been used in more than eight million procedures, worldwide and is supported by an ever-growing body of evidence-based research. The clinical efficacy, consistency and reliability of LigaSure™ products is delivered through a variety of instruments for use in both laparoscopic and open procedures.

**Ultrasonic Energy**
The Covidien Sonicision™ cordless ultrasonic device brings ultrasonic technology, with the expected reliable performance of Covidien Energy to the operating theater. Power efficiency with the award-winning Soncitison™ device removes the cords, simplifies set-up, allows for a reduction in instrument exchanges and provides more available space in the operating room without the need for a separate generator.
Why LigaSure™ Technology

LigaSure™ technology is supported by over 300 peer-reviewed clinical studies and over eight million procedures.

Compared to mechanical ligation techniques, LigaSure™ technology has been shown to significantly reduce:

- Operative blood loss in colorectal gynecologic and urologic surgery\(^1\)-\(^6\)
- Perioperative blood transfusions in gynecologic, urologic and general surgery\(^5,\)\(^7\)
- Procedure time in colorectal, gynecologic and urologic surgery\(^1,\)\(^3,\)\(^4,\)\(^6,\)\(^9\)
- Length of hospital stay in gynecologic and urologic surgery\(^3,\)\(^10\)

Compared to other energy-based modalities, LigaSure™ technology has been shown to reduce:

- Operative blood loss in colorectal and gynecologic surgery\(^11-14\)
- Procedure time in colorectal and gynecologic surgery\(^14\)
I am requesting the following instruments be stocked in our facility so that I have consistent access to these devices for my cases:

- LigaSure™ Maryland jaw 20 cm open sealer/divider (LF1723)
- LigaSure™ Maryland jaw 37 cm laparoscopic/sealer/divider (LF1737)
- LigaSure™ Maryland jaw 44 cm long laparoscopic/sealer/divider (LF1744)

The LigaSure™ Maryland jaw is a multifunctional device that combines one-step sealing and the functionality of a Maryland dissector, atraumatic grasper and cold scissors with the safety of LigaSure™ technology, which seals vessels, up to and including 7 mm, lymphatic, pulmonary vasculature and tissue bundles in 2 to 4 seconds using the ForceTriad™ energy platform. The LigaSure™ Maryland jaw also provides enhanced blunt dissection and allows for cutting independent of sealing.5

LigaSure™ instruments have been found to:

- Have the highest burst pressure and fastest sealing time, and were highest rated overall compared to Gyrus PK™*, Harmonic ACE™* and ENSEAL™*1
- Reduce blood loss compared to sutures and clips. 2, 3, 4
- Reduce procedure time compared to sutures. 2, 3
- Reduce patient length of stay compared to sutures2
- More than 300 studies have been published about LigaSure™ technology in peer-reviewed journals.

In addition, user feedback for this device has been positive:

- 100% of surgeons surveyed after using the device believe that the LigaSure™ Maryland jaw device provides efficiency throughout the procedure.5
- 100% of General surgeons surveyed after using the LigaSure™ Maryland jaw device agreed that it will reduce instrument exchanges during surgery.5

I am confident in using a technology backed by such a significant body of evidence-based research and positive peer feedback. Thank you for reviewing this information. Please feel free to contact me if you have any questions.

Sincerely,

Additional Comments:

References
5. Based on independent surgeon feedback collected during Covidien-sponsored labs conducted April 16-18, 2013 and April 30-May 3, 2013.
LigaSure™ Maryland jaw open/laparoscopic sealer/divider is a **multifunctional device** that delivers **efficiency and versatility** by combining **one-step sealing** and the functionality of a Maryland dissector, autraumatic grasper, and cold scissors with the **reliability of LigaSure™ technology**.
In addition to the 37 cm, multiple lengths provide standardization across procedures:

- 23 cm provides access in deep and confined spaces
- 44 cm provides additional reach

### Ordering Information

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<tr>
<th>Catalog Number</th>
<th>Quantity Per Package</th>
<th>Product Description</th>
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<tr>
<td>LF1723</td>
<td>6 each</td>
<td>LigaSure™ Maryland Device – 23 cm</td>
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<td>LF1737</td>
<td>6 each</td>
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<tr>
<td>LF1744</td>
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LigaSure™ Maryland jaw combines one-step sealing with the functionality of a Maryland dissector, atraumatic grasper and cold scissors with the reliability of LigaSure™ technology.

**EFFICIENT**
- One-step sealing provides efficient transection speed\(^2\)\(^5\)
- Design allows for minimal steps when sealing and dividing\(^2\)\(^5\)
- The actions to grasp, seal and cut are simple and intuitive\(^2\)\(^5\)

**VERSATILE**
- Enhanced blunt dissection\(^2\)\(^5\)
- Improved tip visualization\(^2\)\(^5\)
- Reduced instrument exchanges\(^2\)\(^5\)

**MULTIFUNCTIONAL**
- A Maryland dissector, grasper and cold scissors all from one device\(^2\)\(^5\)
- Consistency, control and safety of LigaSure™ technology
Portfolio
Advantages
Surgeon Feedback

After using the LigaSure™ Maryland device:  

- 100% of general surgeons surveyed agreed that it will reduce instrument exchanges in surgery
- 90% of general surgeons surveyed agreed that the integrated cutter will reduce the need for additional cold scissors
- 80% of general surgeons surveyed agreed that the device will reduce the need for additional dissecting instruments
- The majority** of surgeons surveyed agreed that the secure and atraumatic grasping will reduce the need for an additional grasper
- 100% of surgeons surveyed after using the instrument believe that the LigaSure™ Maryland device provides efficiency throughout the procedure

<table>
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<th>Potential Cost Savings Example</th>
<th>Maryland Dissector</th>
<th>Grasper</th>
<th>Shears</th>
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<td>Average price for disposable device</td>
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<td>$65</td>
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<td>Number of Maryland dissectors per case</td>
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<td>Number of cases per week</td>
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<td>Number of operating weeks per year</td>
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<td>Cost savings, per year, if eliminated</td>
<td>$42,000</td>
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Potential savings of $116,500 per account annually!

**17 of the 33 surgeons surveyed
Portfolio Consolidation

Replacing duplicate vessel sealers and disposables with the LigaSure™ Maryland jaw could:

- Reduce SKU inventory management
- Reduce capital equipment burden by eliminating duplicate generators requiring maintenance and storage
- Reduce the number of meetings with different suppliers
- Qualify your facility for a preferred tier pricing
# Product Comparison

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<th>Seal Plate Length (mm)</th>
<th>LF1737 LigaSure™ Maryland jaw</th>
<th>LF1212 LigaSure™ small jaw</th>
<th>LS1500 LigaSure™ Dolphin Tip</th>
<th>LF1637 LigaSure™ Blunt Tip</th>
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<tr>
<td></td>
<td>20.3</td>
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| Cut Length (mm)       | 18.5                          | 15.2                       | 14.0                        | 16.8                      |
| Jaw Curvature (degrees) | 22                            | 30                         | Straight                    | Straight                  |

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<td><strong>ENSEAL™</strong></td>
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Competitive Cross References
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<td>No</td>
<td>No</td>
<td>Ethicon Endo-Surg Gen11</td>
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<td>Ethicon</td>
<td>ENSEAL™* G2 Straight Tissue Sealer - 45 cm</td>
<td>NSLG2S45</td>
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<td>THUNDERBEAT™*, 5 mm - 45 cm, Front-Actuated Grip</td>
<td>TB-0545FC</td>
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<td>PKS™* Cutting Forceps, 5 mm - 45 cm</td>
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<td>PKG400 Workstation</td>
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References
References

17. Compared to standard length laparoscopic devices
Appendix
510(k) Clearance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Covidien
Mr. Donald Henton
Regulatory Affairs Manager
5920 Longbow Drive
Boulder, Colorado 80301

Re: K133338
Trade/Device Name: LigaSure™ 5 mm Maryland Jaw Sealer/Divider
One-step Sealing (LF17XX series)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 29, 2013
Received: October 30, 2013

December 20, 2013

Dear Mr. Henton:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications For Use

Indications for Use Statement

510(k) Number (if known): K133338

Device Name: LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing (LF17XX series)

Indications for Use:

The LigaSure™ 5 mm, Maryland Jaw, Open / Minimally Invasive Sealer/Dividers are bipolar electrosurgical instruments intended for use with the ForceTriad™ Energy Platform in general, minimally invasive and open surgical procedures where ligation and division of vessels and lymphatics is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Indications for use include general open and minimally invasive procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of the vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The LigaSure 5 mm Maryland Jaw Sealer/Dividers can be used on vessels and lymphatics up to and including 7 mm, and tissue bundles.

Prescription Use AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen

-Division Sign-off-

Division of Surgical Devices

510(k) Number: K133338

510(k): LigaSure™ 5 mm Maryland Jaw Sealer/Divider One-step Sealing – LF17XX series