VALUE ANALYSIS BRIEF

ForceTriad™ Energy Platform
I am requesting that the ForceTriad™ energy platform be implemented in our facility so that I may have consistent access for my cases.

The ForceTriad™ energy platform is a full-featured electrosurgical system that provides electrosurgical cutting and coagulation, bipolar functionality, and vessel sealing in a single generator. The ForceTriad™ energy platform is intended for open and laparoscopic surgical procedures and includes:

- TissueFect™ sensing technology across all modalities
- Valleylab™ mode for electrosurgery
- LigaSure™ fusion technology for vessel sealing

The ForceTriad™ energy platform is the industry's only full-featured energy platform with remote software upgrade capabilities. Using the Valleylab™ Exchange Software Update System, the ForceTriad™ energy platform can be easily updated on site, providing surgeons, nurses and patients with up-to-date, state-of-the-art technology.

The ForceTriad™ energy platform delivers ground-breaking LigaSure™ tissue fusion technology for vessel sealing. LigaSure™ technology seals vessels up to and including 7 mm, lymphatics, pulmonary vasculature and tissue bundles in 2 to 4 seconds on average when using the ForceTriad™ energy platform.

The ForceTriad™ energy platform provides the operating room with one energy platform meeting your electrosurgical and tissue fusion needs. Specialties utilizing the ForceTriad™ energy platform include:

Colorectal  Urology  Orthopedics
General Surgery  Plastics  Gynecology

Thank you for reviewing this information. Please feel free to contact me if you have any questions.

Sincerely,
**ForceTriad™ Energy Platform**

**Overview**
The ForceTriad™ energy platform combines monopolar electrosurgery, bi-polar electrosurgery and vessel sealing in a single generator intended for open and laparoscopic surgical procedures. This all-in-one generator is compatible with conventional electrosurgical instruments as well as all current LigaSure™ devices.

**Specialties**
- Colorectal
- Urology
- Orthopedics
- General Surgery
- Plastics
- Gynecology

**Order Information**

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**Features**
- TissueFect™ sensing technology
- Valleylab™ mode for electrosurgery
- Enhanced LigaSure™ tissue fusion for vessel sealing
- Closed-loop monopolar control
- Built-in ammeter
- Automatic instrument recognition
- Touch screen technology
- Valleylab™ Exchange Software Update System
- Electrosurgical connectivity/compatibility with da Vinci® Surgical System
- Autobipolar capability
- PER of 98 in Cut
- Connects with RapidVac™ smoke evacuator
- Adaptive REM™ system
TissueFect™ Sensing Technology

TissueFect™ sensing technology is the operating system that powers all the ForceTriad™ energy platform functions and is designed to precisely manage energy delivery, creating a range of options for improved desired tissue effect and consistent power delivery.

Valleylab™ Mode for Electrosurgery

“As a true intermediary mode, the Valleylab™ mode divides tissue efficiently while maintaining hemostasis and minimizing thermal injury to surrounding tissues. This mode minimizes the disadvantages of the Cut and Fulgurate modes while maximizing control. The Valleylab™ mode is a superior choice for all applications where more control is needed for maintaining hemostasis while dividing tissues.”

LigaSure™ Vessel Sealing

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

- Significantly reduce operative blood loss in colorectal, gynecologic and urologic surgery²-⁵,⁷
- Significantly reduce perioperative blood transfusions in gynecologic, urologic and general surgery⁶,⁸,⁹
- Significantly reduce procedure time in colorectal, gynecologic and urologic surgery²,⁴,⁵,⁷,¹⁰,¹¹

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

- Significantly reduce operative blood loss in colorectal and gynecologic surgery¹²,¹³,¹⁵
- Significantly reduce procedure time in colorectal and gynecologic surgery¹²,¹⁵

**Compared to previous versions of LigaSure™ technology, the ForceTriad™ energy platform has been shown to:**

- Provide a quicker seal, no tissue–fusion failures, less bleeding and less thermal spread¹⁶

References

LigaSure™ Vessel Sealing System

1. **Submitter Information**

Valleylab  
A Division of Tyco Healthcare Group LP  
5920 Longbow Drive  
Boulder, CO 80301  
Contact: Philip E. Ake  
Senior Regulatory Associate  
Telephone: 303-581-6808  
Fax: 303-530-6313  
E-mail: Philip.Ake@TycoHealthcare.com  

Date summary prepared: January 16, 2007

2. **Name of Device**

*Trade or Proprietary Name:* ForceTriad™ Electrosurgical Generator  
*Common/Classification Name:* Electrosurgical Cutting and Coagulation Device and Accessories

3. **Predicate Devices**

The ForceTriad™ Electrosurgical Generator is substantially equivalent to the following legally marketed medical devices:

- ForceTriad™ Electrosurgical Generator (K051644)

4. **Device Description**

The ForceTriad™ generator is a full-featured electrosurgical generator with monopolar, bipolar, and Valleylab LigaSure™ vessel sealing outputs. This 510(k) only applies to the LigaSure™ Vessel sealing portion of the generator. The generator is electrically isolated, microcontroller-based device, incorporating closed-loop control for all output modes implemented in the microcontroller firmware. The generator incorporates Instant Response™ technology to constantly measure the electrical impedance of the tissue and instantaneously adjust the generator output to maintain the desired power.

The generator is used with a selection of instruments designed for use with the ForceTriad and the LigaSure Vessel Sealing generator. All of the instruments are capable of sealing vessels up to, and including, 7mm, and tissue bundles as large as can fit in the jaws of each instrument. When a LigaSure™ instrument is applied to a vessel or tissue bundle and RF energy is applied, the collagen and elastin in the tissues are reformed by heat and pressure to fuse vessel walls, thereby forming a permanent seal. The microprocessor in the generator monitors the tissue properties, stops the
application of energy, and allows a brief period of cooling before indicating that the seal cycle is complete.

No changes are being made to the design or operation of any of the devices within the current system. The change as proposed in this 510(k) notification is to the intended use as described above and the resulting labeling changes.

5. Intended Use

The ForceTriad™ is a full-featured electrosurgical generator intended for open and laparoscopic surgical procedures where the surgeon requires electrosurgical cutting, coagulation, or vessel sealing (tissue fusion). The generator is intended for use in general, laparoscopic and gynecologic surgical procedures where ligation of vessels, pulmonary vasculature, or lymph vessels, is desired. The system creates a vessel ligation (seal) by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

The indications for use include general (including urologic, thoracic, plastic and reconstructive), laparoscopic, and gynecological procedures where electrosurgical cutting and coagulation of tissue, and sealing (fusion) of vessels, including pulmonary vessels, and tissue bundles is performed, including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins, lymph) up to 7mm and bundles as large as will fit in the jaws of the instruments.

The LigaSure tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

6. Summary of Technological Characteristics

The technological characteristics of the ForceTriad Electrosurgical generator have not been modified.

7. Performance and Clinical Data

Pre-clinical studies (acute and chronic) and bench testing have shown that the ForceTriad Electrosurgical Generator effectively seals pulmonary vasculature, producing seals with burst pressures substantially greater than the physiologic pressures in the vessels.
Valleylab, a Division of Tyco
Healthcare Group LP
% Mr. Philip E. Ake
Senior Regulatory Associate
5920 Longbow Drive
Boulder, Colorado 80301

Re: K070162
Trade/Device Name: Force Triad™ Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 16, 2007
Received: January 17, 2007

Dear Mr. Ake:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Device Name: ForceTriad™ Electrosurgical Generator

Indications For Use:

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Prescription Use ✓ AND/OR Over-the-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of General, Restorative, and Neurological Devices

510(k) Notification: ForceTriad™ Electrosurgical Generator

510(k) Number 107016