K111600

SECTION 5: 510(k) SUMMARY

NOV 15 2011

Submitter:

Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

Ramona Kulik
Regulatory Affairs Engineer
480.763.5300 (o)
480.763.2952 (f)
rkulik@ascenths.com

Date of preparation: June 7, 2011

Name of device:

Trade/Proprietary Name: Reprocessed Hand Activated Sealer/Divider

Classification Name: Electrosurgical cutting and coagulation device and accessories

Predicate Device	**510(k) Title**	**Manufacturer**
K070162	Forcetriad Electrosurgical Generator; Ligasure Instruments	Valleylab A division of Tyco Healthcare Group

Device description: The Hand Activated Sealer/Divider is an instrument that works exclusively with the ForceTriad™ energy platform (not within the scope of this submission) to seal vessels up to and including 7 mm, seal pulmonary vasculature, lymphatics and tissue bundles. The instrument's shaft diameter is 13.5 mm (oval), length is 18 cm and shaft rotation is 180 degrees.

Indications for Use: The Reprocessed Hand Activated Sealer/Divider can be used during open procedures to seal vessels up to and including 7mm, lymphatics and tissue bundles. The Hand Activated Sealer/Divider can also be used to seal pulmonary vasculature but only when used with the ForceTriad™ energy platform.
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.

Technological characteristics:

The design, materials, and intended use of the Reprocessed Hand Activated Sealer/Divider are identical to the predicate device. The mechanism of action of Reprocessed Hand Activated Sealer/Divider is identical to the predicate device in that the same standard mechanical design, size, and materials are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions' reprocessing of the Hand Activated Sealer/Divider includes removal of adherent visible soil and decontamination. Each individual Hand Activated Sealer/Divider 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 Hand Activated Sealer/Divider. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Hand Activated Sealer/Divider perform as originally intended.

Conclusion:

Ascent Healthcare Solutions concludes that the Reprocessed Hand Activated Sealer/Divider are safe, effective, and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ascent Healthcare Solutions
% Ms. Ramona Kulik
10232 South 51st Street
Phoenix, Arizona 85044

NOV 15 2011

Re: K111600
Trade/Device Name: Reprocessed Hand Activated Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: November 09, 2011
Received: November 14, 2011

Dear Ms. Kulik:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111600

Device Name: Reprocessed Hand Activated Sealer/Divider

Indications For Use:
The Reprocessed Hand Activated Sealer/Divider can be used during open procedures to seal vessels up to and including 7mm, lymphatics and tissue bundles. The Hand Activated Sealer/Divider can also be used to seal pulmonary vasculature but only when used with the ForceTriad™ energy platform.
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.

Prescription Use __X____ 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111600