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K093702

SECTION 5: 510(k) SUMMARY

Submitter:

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

Contact:

Moira Barton-Varty
Senior Director Regulatory Affairs
480.763.5300 (o)
480.763.5350 (f)
mbarton@ascenths.com

Date of preparation: November 30, 2009

Name of device:

Trade/Proprietary Name: Reprocessed Ultrasonic Coagulating Shears
Classification Name: Scalpel, Ultrasonic, Reprocessed

Predicate Device	510(k) Title	Manufacturer
K062000	Harmonic Wave Coagulating Shears With Scissor Handle and Hand Control, Model Wave18S; Harmonic Disposable Torque Wrench	Ethicon Endo-Surgery, Inc.

Device description:

The Ultrasonic Coagulating Shears is an instrument consisting of a scissor handle housing assembly with hand control buttons (MIN for minimum power level and MAX for maximum power level). An audible and tactile mechanism is integrated into the handle housing to indicate full closure. The Ultrasonic Coagulating Shears is 18 cm long, shaft diameter of 8.5 mm, with an active blade length of 18 mm. The blade and clamp arm are straight allowing them to function through an incision without the use of a trocar. The Ultrasonic Coagulating Shears allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

The Ultrasonic Coagulating Shears is designed to operate with the Harmonic ™ Generator 300 (GEN04) and the Hand Piece (HP054).

Note: Only the Ultrasonic Coagulating Shears is the subject of this submission, the reusable hand piece, generator, and any other related equipment are not included in the scope of this submission.

Indications for Use: The Reprocessed Ultrasonic Coagulating Shears with Scissor Handle and Hand Control are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The shears can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures and other open procedures.

Technological characteristics: The design, materials, and intended use of Reprocessed Ultrasonic Coagulating Shears are identical to the predicate device. The mechanism of action of Ultrasonic Coagulating Shears 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 Ultrasonic Coagulating Shears includes removal of adherent visible soil and decontamination. Each individual Ultrasonic Coagulating Shear 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 Ultrasonic Coagulating Shears. This included the following tests:

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

Performance testing demonstrates that Reprocessed Ultrasonic Coagulating Shears perform as originally intended.

Conclusion: Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Ultrasonic Coagulating Shears) 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 W-O66-0609
Silver Spring, MD 20993-0002

MAR - 4 2010

Ascent Healthcare Solutions
% Ms. Moira Barton-Varty
Senior Director of Regulatory Affairs
10232 South 51st Street
Phoenix, Arizona 85044

Re: K093702
Trade/Device Name: Reprocessed Ultrasonic Coagulating Shears
Regulatory Class: Unclassified
Product Code: NLQ
Dated: February 23, 2010
Received: February 24, 2010

Dear Ms. Barton-Varty:

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.

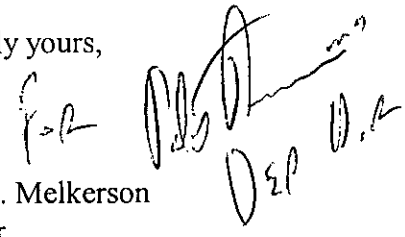
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K 0 9 3 7 0 2

Device Name: Reprocessed Ultrasonic Coagulating Shears

Indications For Use:
The Reprocessed Ultrasonic Coagulating Shears with Scissor Handle and Hand Control are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The shears can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures and other open 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)

Neil R P Ogden for mxn

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

510(k) Number K093702

Reprocessor	Model Number	Description
Ascent Healthcare Solutions	Wave18S	Reprocessed Ultrasonic Coagulating Shears Scissor Handle with Hand Control 8.5 mm diameter / 18 cm long

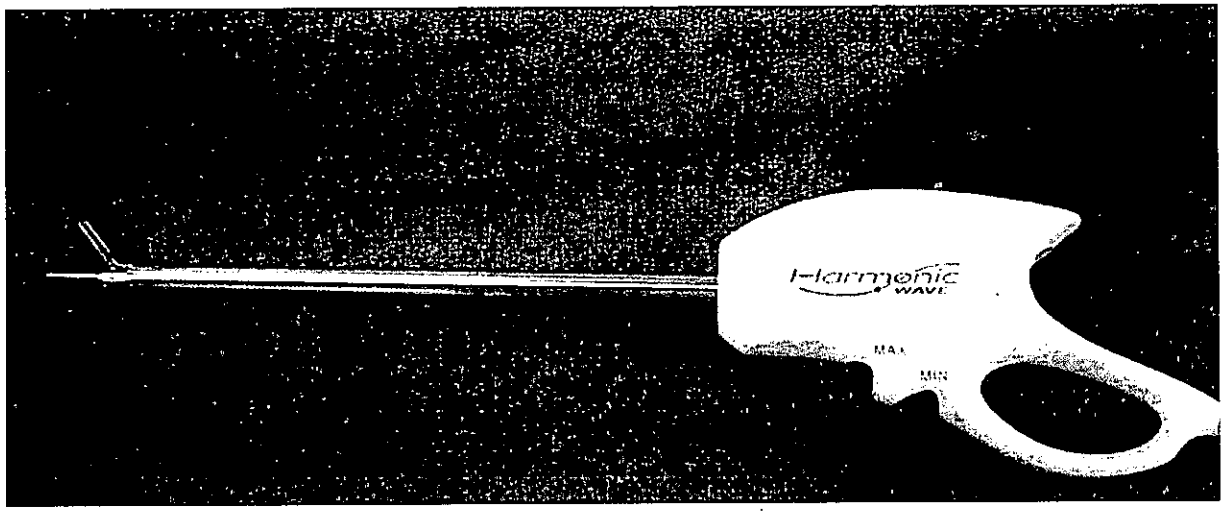


Figure 1 Reprocessed Ultrasonic Coagulating Shears

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

510(k) Number K093702