K181057

510(k) Summary of Safety and Effectiveness

APR - 5 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, 21 CFR 807.87, 21 CFR 807.92, Format for Traditional and Abbreviated 510(k)s.

1. Name of Submitter, Contact Person and Date Summary Prepared:

Company Name:	Salient Surgical Technologies, Inc.
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Contact:	Tara N. Turney Urling, RAC Senior Regulatory Affairs Specialist
Date of Preparation:	March 29, 2011

2. Device Trade Name and Common Name:

Trade Name:	Aquamantys Double Cone Bipolar Sealer
Common/Usual Name: Classification Name: Accessories	Electrosurgery Bipolar Sealer Electrosurgical, Cutting & Coagulation &

3. Product Code: GEI
21CFR 878.4400

Device Class: Class II

4. Legally Marketed Equivalent Device: TissueLink Solid Cylinder Monopolar Device
510(k) K014260

Aquamantys Pump Generator System
(including AQM Bipolar Sealers 2.3 and 6.0)
510(k) K052859

5. Performance Standards: None applicable

6. Description of the Device: The Aquamantys Double Cone Bipolar Sealer is a disposable, single-use, sterile, bipolar device. The device employs radio-frequency (RF) energy and saline irrigation for hemostatic sealing and for coagulation and blunt dissection. The device is equipped with a dual electrode tip. Saline and electrical lines exit the opposite end of the handpiece from the electrodes. The handpiece is equipped with an on-off button that simultaneously activates both RF and saline flow. A saline fluid delivery line is provided with the device, and includes a section of pump tubing and a drip chamber or spike. The three-pin electrical connector is designed to be plugged into the Aquamantys Pump Generator.

7. Intended Use of the Device: The Aquamantys Double Cone Bipolar Sealer is a single use, sterile, bipolar device, intended to be used in conjunction with the Aquamantys Pump Generator for delivery of radio-frequency (RF) energy and saline for blunt dissection and for haemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to, open abdominal, orthopaedic, and thoracic surgery.

   The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

8. Comparison of technological characteristics with Predicate Device: The device is similar to the TissueLink Solid Cylinder Monopolar device in that it is capable of blunt dissection as well as hemostatic sealing and coagulation. Physically, the device employs similar characteristics to the Aquamantys 6.0 Bipolar Sealer including connection to the Aquamantys Pump Generator.

9. Pre-Clinical Evaluation: Where applicable, non-clinical testing of the proposed device relied upon to determine substantial equivalence to the predicate were as follows:
   - In-vivo porcine testing, including:
     - Tissue resection showing depth versus fluence
     - Stationary depth of effect on tissue versus time
     - Moving depth and diameter of effect versus time
     - Usability
       - Angle of usage
       - Various tissue usage states
       - Compatibility with appropriate generator
       - Finger switch
   - Electromagnetic Compatibility per IEC 60601-1-2 as modified by IEC 60601-2-2
   - Visual and Dimensional

Testing has confirmed the proposed device's performance for blunt dissection and for haemostatic sealing and coagulation is at least as safe and effective as that of the predicate devices.

10. Conclusion: The proposed and predicate devices have similar intended uses, similar design, performance and functional features as well as the same fundamental scientific technology. The proposed device is found to be substantially equivalent to the named predicates.

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

Salient Surgical Technologies, Inc.
% Regulatory Technology Services LLC
Mr. Mark Job
1394 25th Street NW
Buffalo, MN 55313

APR - 5 2011

Re: K101057
Trade/Device Name: Aquamantys Double Cone Bipolar Sealer
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 1, 2011
Received: April 4, 2011

Dear Mr. Job:

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

510(k) Number (if known): K101057

Device Name: Aquamantys Double Cone Bipolar Sealer

Indications for Use: The Aquamantys Double Cone Bipolar Sealer is a single use, sterile, bipolar device, intended to be used in conjunction with the Aquamantys Pump Generator for delivery of radio-frequency (RF) energy and saline for blunt dissection and for haemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to, open abdominal, orthopaedic, and thoracic surgery.

The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(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 K101057