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OCT 25 2005

K052859

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Application Information:

Date Prepared:	September 29, 2005
Submitter:	TissueLink Medical Inc.
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Contacts:	Vicki S. Anastasi Director of Regulatory Affairs
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Device Information:

Trade Name:	Aquamantys Pump Generator System, Aquamantys 6.0 Bipolar Sealer, and Aquamantys 2.3 Bipolar Sealer
Common Name:	Electrosurgical Bipolar Generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories - 21CFR 878.4400

Predicate Devices:

Claim of Substantial Equivalence of the Aquamantys Pump Generator System is made to:

Name:	Söring GmbH MBC™ Series
510(k) Number	K#024059
Regulation Number	878-4400 Device, Electrosurgical, Cutting & Coagulation & Accessories
Product Code	GEI
Decision Date	January 8, 2003

Claim of Substantial Equivalence of the Aquamantys 6.0 and 2.3 Bipolar Sealer devices are made to:

TissueLink BPS 6.0 K20574 and K022532
TissueLink BPS 2.3 K032132

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Device Description-Pump Generator

The Aquamantys Pump Generator is a shelf top unit consisting of a sheet metal housing, front control panel and side mounted peristaltic pump. Within the housing resides a main circuit board, a display circuit board, a power supply board, a power transformer and the pump motor. The proprietary software integrates the flow to the desired power setting and flow level selected. The pump generator can be set from 20 to 200 watts and has high, medium and low flow rate settings.

The Aquamantys system includes the pump generator, cart and specified Aquamantys disposable devices. The Aquamantys BPS 6.0 and the Aquamantys BPS 2.3 are hand held "wand" like devices that consist of a plastic handle with two metal tipped probes protruding from one end that interface with the operative site. These devices have an electrical connector that plugs into the pump generator and have a section of pump tubing that clamps into the peristaltic pump.

Compared to most conventional electrosurgical devices and generators, TissueLink bipolar technology is based on simultaneous saline irrigation and RF power delivery, as well as the treatment of tissue that is not typically treated by surgeons – large areas of cut tissue that are oozing blood at a slow but steady rate.

A complete Aquamantys System diagram is shown on the following page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2005

Vicki S. Anastasi
Director of Regulatory Affairs
TissueLink Medical, Inc.
One Washington Center, Suite 400
Dover, New Hampshire 03820

Re: K052859
Trade/Device Name: TissueLink Aquamantys Pump Generator System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 7, 2005
Received: October 11, 2005

Dear Ms. Anastasi:

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" (21CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

K052859

Indications for use Statement

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510(k) Number (if known): K052859

Device Name: TissueLink Aquamantys Pump Generator System

Indications for Use:

The Aquamantys™ Bipolar Pump Generator is an electrosurgical generator with a rotary peristaltic pump which is for use only with Aquamantys single-use disposable bipolar devices for concurrent delivery of radiofrequency energy with saline for hemostatic sealing of soft tissue and bone at the operative site. It is intended for, but not limited to, endoscopic and open abdominal, orthopaedic, spine and thoracic surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).
The Aquamantys System is for use only by qualified medical personnel properly trained in the use of electrosurgical equipment, technology and techniques.

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109) Optional Format 1

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ann MD

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

510(k) Number K052859