K110439

JUL 18 2011

510(k) SUMMARY

Domain Surgical System
Date of Summary: February 7, 2011

General Provisions

Submitter's Name:	Domain Surgical
Submitter's Address:	1370 South 2100 East Salt Lake City, Utah 84108
Contact Person:	Curtis Jensen, Director of Quality and Regulatory Affairs
Phone Number:	(801) 924-4958
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Proprietary Name:	Domain Surgical System
Common Name:	Electrosurgical cutting and coagulation device and accessories

Name of Predicate Device(s)

- Hemostatix Medical Technologies, LLC - Model P8400 Hemostatix Thermal Scalpel System, (Product Code GEI) 510(k) #K091107
- Valleylab Force 2 Electrosurgical Generator (Product Code GEI) 510(k) #K844403

Device Description

An electrosurgical cutting and coagulation device (and accessories) is a device intended to remove tissue and control bleeding by use of high-frequency electrical current (21 CFR §878.4400). It is classified as a Class II (510(k)) device.

The Domain Surgical System is a soft tissue cutting and coagulation device that consists of a generator that is electrically connected to a sterile, single-use handpiece and an optional footswitch. Like the predicate devices, the handpiece includes an actuation button that can be used to activate heating in the handpiece tip. Also like the predicate devices, an optional footswitch can be used to activate the handpiece.

Technological Comparison

The Domain Surgical System employs ferromagnetic heating to generate heat in the handpiece tip. This method of heating differs from the predicate device (Hemostatix Thermal Scalpel System), which employs only the electrical resistance of the materials in the handpiece tip to produce heat. The Domain Surgical System differs from the Hemostatix device in that it employs active cooling of the handpiece, outputs a unique generator electrical waveform and the provided footswitch specifies a different moisture resistance rating. It differs from the Valleylab device in that no current is passed through the patient and the impedance of the tissue is not employed to create the heat necessary to cut and coagulate soft tissue. The Domain device also differs from the Valleylab device in that it employs active cooling of the handpiece and outputs a unique generator electrical waveform.

Indications for Use

Indications for Use: The Domain Surgical System is indicated for cutting and coagulation of soft tissue.

The indications for use statement for the Domain Surgical System is the same as the predicate devices with minor differences that provide clarity and have no effect on safety or effectiveness.

Safety and Biocompatibility Summary

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other similar devices on the market. Bench testing was performed with the Domain Surgical System to assure that it functions as intended. Bench tests verified that the generator output was within specification and that the thermal output of the handpiece tip corresponds to the target values. It was also tested by an accredited independent testing laboratory to assure that it complies with the applicable electrical safety standards for medical electrosurgical devices, including the applicable sections of IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-2.

The software that controls the operation of the generator has undergone proper design verification and validation to assure that it meets design requirements and operates safely and effectively for the device's intended use, including controlling output power and providing audio and visual information during use.

The patient contacting materials used in the Domain Surgical System were chosen for their biocompatibility, function and suitability for the intended use of this device. Successful biocompatibility testing of applicable parts of the system was completed by accredited independent testing laboratories according to ISO 10993-1 and 510(k) Memorandum G95-1. Live animal testing was performed that demonstrates that the Domain Surgical System is as effective at cutting and coagulating soft tissue as other legally marketed electrosurgical devices.

Conclusion

The Domain Surgical System is substantially equivalent to the Hemostatix Model P8400 Thermal Scalpel System (510(k)# K091107) and the Valleylab Force 2 Electrosurgical Generator (510(k) #K844403). The intended use of the Domain Surgical System is the same as the predicate devices, with the exception of the 'vessel sealing' claim by the Henostatix System. Furthermore, the indications for use statement is the same as the predicate devices with only minor differences that provide clarity and have no effect on safety or effectiveness. The Domain Surgical System differs from the predicate devices in technological characteristics; however the differences do not raise different types of questions of safety and effectiveness. The information presented in the 510(k), including the bench and animal testing, demonstrates that the Domain Surgical System is as safe and effective as the predicate device for its intended use.

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

JUL 18 2011

Domain Surgical, Inc.
% Mr. Curtis Jensen
1370 South 2100 East
Salt Lake City, Utah 84108

Re: K110439
Trade/Device Name: Domain Surgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 01, 2011
Received: July 05, 2011

Dear Mr. Jensen:

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

Indications for Use

510(k) Number (if known): _____

Device Name: Domain Surgical System

Indications for Use: The Domain Surgical System is indicated for cutting and coagulation of soft tissue.

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 K110439