K102983

NOV - 1 2010

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510(k) Summary

SUBMITTER: Sorin Group USA, Inc.
14401 W. 65th Way
Arvada, CO 80004

CONTACT PERSON: Scott Light
Regulatory Affairs Manager
Phone: (303) 467-6313
Fax: (303) 467-6502

DATE PREPARED: September 30, 2010

DEVICE TRADE NAME: VascuClear Precision Bipolar

COMMON/USUAL NAME: Electrosurgical Instruments

CLASSIFICATION NAME: Electrosurgical, cutting & coagulation & accessories

CLASSIFICATION: Class II (Product Code GEI)

PREDICATE DEVICE: ClearGlide Precision Bipolar (K003587)

DEVICE DESCRIPTION:

The VascuClear Precision Bipolar is a sterile, bipolar electrosurgical instrument with features to dissect, coagulate, and transect (cut) tissue with an integral knife blade. The device is compatible with a 5mm trocar and utilizes bipolar energy from standard bipolar generators.

The instrument consists of three main parts as follows:

1. A handle with two sliding buttons. One button opens and closes the jaw of the device for grasping and clamping. The other button moves the integral knife blade back and forth. A standard pigtail cord is attached to the handle.
2. A shaft that connects the handle to the working end. The shaft is approximately 0.2 inches (5mm) in diameter and 16.5 inches (42cm) long from the handle to the tip of the instrument.
3. The working end of the instrument that consists of jaws, electrode surfaces and an integral knife with a dissecting tip.

INDICATIONS FOR USE:

The VascuClear Precision Bipolar is indicated for endoscopic and open tissue dissection, bipolar coagulation, and transaction of vessels.

TECHOLOGICAL CHARACTERISTICS:

The technological characteristics and principles of operation of the modified device are the same as the predicate device. Both instruments consist of the same main components; a handle with two slide buttons, a two pin electrical connector, a stainless steel shaft, jaws with bipolar electrodes and an integral knife blade. Both instruments have mechanical jaws to grasp tissue and vessels. The "Clamp" button is used to open and close the jaws. The shape and material of the upper jaw was changed to improve its strength. The color of the upper jaw was changed from clear to blue to improve its visibility during use. Both instruments have a sharp edged knife to dissect tissue and transect vessels. The "Cut" button is used to move the knife blade back and forth. Coagulation occurs between electrode surfaces located within the jaws on both instruments. Coagulation energy is controlled externally for both instruments. Springs were added to the buttons to improve the ergonomics of the instrument for ease of use.

NON-CLINICAL PERFORMANCE DATA:

Testing was performed to confirm that the modifications function as intended and did not adversely affect the operation of the instrument. Electrical safety and biocompatibility testing were also performed to confirm the safety and effectiveness of the VascuClear Precision Bipolar.

CONCLUSIONS:

The VascuClear Precision Bipolar has the same intended use, principles of operation and technological characteristics as the predicate device. The VascuClear is substantially equivalent to the ClearGlide Precision Bipolar.

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

Sorin Group USA, Inc.
% Mr. Scott Light
Regulatory Affairs Manager
14401 West 65th Way
Arvada, Colorado 80004

NOV - 1 2010

Re: K102983
Trade/Device Name: VascuClear Precision Bipolar
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 29, 2010
Received: October 07, 2010

Dear Mr. Light:

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,

For Mark N. Melkerson DEP DIR

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

NOV - 1 2010

510(k) Number (If known): K102983

Device Name: VascuClear Precision Bipolar

Indications For Use:

The VascuClear Precision Bipolar is intended for endoscopic and open tissue dissection, bipolar coagulation, and transection of vessels.

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

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