510(k) SUMMARY (As Required per 21 CFR 807.92(c))

K092383

MAR 10 2010

GENERAL INFORMATION:

510k Owner's Name **Address**	Bovie Medical 5115 Ulmerton Road Clearwater, Florida 33760-4004
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs Telephone #: (727) 803-8513 FAX Number: (727) 322-4465
Date Prepared:	07/31/2009

DEVICE DESCRIPTION:

Trade Name:	Bovie ICON VS Electrosurgical Generator
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code GEI)
Predicate Devices:	
Bovie Medical	Bovie ICON GP General Purpose RF Generator (K-082109)

K092383

Page 2 of 2

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DEVICE OPERATION:

The ICON VS Electrosurgical Generator is intended to be used with Bovie Seal and Cut Instruments for sealing vessels and cutting tissues.

There is a characteristic electrical wave form associated with each mode. The electrical properties of the waveform (frequency and duration) produce the clinical effect (i.e. cut, coagulation, and seal). The shape and duration of waveforms are comparable between the generator and the predicate device.

The **Generator** functions in any of the following user selectable modes:

1. Pure Cut
2. Blend Mode 1
3. Blend Mode 2
4. Blend Mode 3
5. Special Cut
6. Laparoscopic Cut
7. Pinpoint Coagulation
8. Gentle Coagulation
9. Spray Coagulation
10. Laparoscopic Coagulation
11. Macro Bipolar
12. Micro Bipolar
13. Gentle Bipolar
14. Auto Stop Bipolar
15. Vessel Seal with Optional Power Cut

The generator is designed to comply with applicable Medical Electrical Equipment safety standards, including electromagnetic compatibility and other safety standards.

Like the predicate device, the ICON VS incorporates an ergonomically designed user interface screen for the selection of device settings. The ICON VS uses identical technology to the predicate device and the waveform profiles for all cut, coagulation, and bipolar modes are identical. The ICON VS differs from the predicate device in that 1) it is designed to work with Bovie Seal and Cut Instruments (K-092208 pending review), 2) the vessel sealing mode on the ICON VS is less aggressive than the predicate device (90 watts of power versus 400 watts of power), and 3) the power cut mode on the ICON VS delivers 100 watts of power versus the predicate device which delivers 80 watts of power.

There are no new hazards presented with the use of the Bovie ICON VS generator as compared with the named predicate device.

INTENDED USE:

The ICON VS Electrosurgical Generator is intended to be used with Bovie Seal and Cut Instruments for sealing vessels and cutting tissues.

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

Bovie Medical Corporation
% Mr. Richard A. Kozloff
Vice President, Quality Assurance/
Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760-4004

MAR 10 2010

Re: K092383
Trade/Device Name: Bovie ICON VS Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 05, 2010
Received: February 12, 2010

Dear Mr. Kozloff:

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): K092383

Device Name: Bovie ICON VS Electrosurgical Generator

Indications for Use:

The ICON VS Electrosurgical Generator is intended to be used with Bovie Seal and Cut Instruments for sealing vessels and cutting tissues.

Prescription Use ✓ 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 MKM

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

510(k) Number K092383