510(k) SUMMARY (per CFR21 807.92(c))

K082568

GENERAL INFORMATION:

NOV 17 2008

510k Owner's Name **Address**	Bovie Medical 7100 30th Avenue North St. Petersburg, Florida 33710-2902
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs Telephone #: (727) 384-2323 FAX Number: (727) 347-9144
Date Prepared:	September 2, 2008

DEVICE DESCRIPTION:

Trade Name:	Saline Enhanced Electrosurgical Resection (SEER) Device
Common Name:	Resection (Cutting and Coagulation) Device
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code: GEI)
Predicate Device:	TissueLink Solid Cylinder Monopolar Device (K-01260)

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DEVICE DESCRIPTION:

Predicate Devices:

TissueLink: Solid Cylinder Monopolar Device K014260

INTENDED USE:

The Resection Device is a sterile, single use electrosurgical device intended to be used in conjunction with an electrosurgical generator for the delivery of radiofrequency ("RF") current and sterile saline for cutting and coagulating soft tissue.

DEVICE COMPONENTS AND OPERATION:

1) Insulated Handle:

The Insulated Handle encases the controlling mechanism for the flow of saline, and activation of the RF current for the device.

The activation of RF current is accomplished by a single push button on the top of the handle.

The Handle has a flow control mechanism so the flow of saline can be regulated by the user within the sterile field. The tubing length is approximately ten (10) feet in length and incorporates an I.V. spike on the end to attach directly to a hanging IV (saline) bag.

The Handle power cord is approximately ten (10) feet in length and incorporates a 3-prong electrical plug.

The insulation of the Insulated Handle and Power Cord meets the requirements for Dielectric Withstands of Accessories.

2) Shaft and Electrode Tip:

The electrode tip delivers RF energy for cutting and coagulation and delivers saline which is gravity-fed from an Intravenous bag to the tip.

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These devices use technology substantially equivalent to the TissueLink Solid Cylinder Monopolar Device (K014260). Both consist of an electrode tip that is used to cut and coagulate tissue through the utilization of high frequency radiofrequency energy.

Resection Devices are provided sterile, sterilized using ethylene oxide gas, and are for single use only.

The Resection Device conforms to the requirements of safety standard IEC 60601-2-2.

There are no significant differences in technology, performance, or intended use between the Resection Device and the given predicate device. There are no new questions raised regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2008

Bovie Medical
% Mr. Richard Kozloff
VP, Quality Assurance/Regulatory Affairs
7100 30th Avenue North
St. Petersburg, Florida 33710-2902

Re: K082568
Trade/Device Name: Resection Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 6, 2008
Received: November 7, 2008

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K082568

Device Name: Resection Device

Indications for Use:

The Resection Device is a sterile, single use electrosurgical device intended to be used in conjunction with an electrosurgical generator for the delivery of radiofrequency ("RF") current and sterile saline for cutting and coagulating soft tissue. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ (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. O'Hara for mxm

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

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