

510(k) SUMMARY

(As Required per 21 CFR 807.92(c))

GENERAL INFORMATION:

510k Owner's Name Bovie Medical Corporation

Address 5115 Ulmerton Road
Clearwater, Florida 33760-4004

Telephone Number: (727) 384-2323

FAX Number: (727) 322-4465

Contact Person Richard A. Kozloff
Vice-President; Quality Assurance/Regulatory Affairs

Date Prepared: August 2, 2011

DEVICE DESCRIPTION:

Trade Name: Bovie® J-Plasma Handpiece with Retractable Cutting Blade

Common Name: Cutting and Coagulation Electrosurgical Device

Classification Name: Electrosurgical Cutting and Coagulation Devices and Accessories

Classification: 21CFR 878.4400; Class II; Product Code GEI

Legally Marketed

Predicate Device(s): Bovie® ICON GS Electrosurgical Handpiece (K090586)

Included Accessories:

	J-Plasma Handpiece with Retractable Cutting Blade	Bovie® ICON GS Electrosurgical Handpiece (Predicate Device)
Reusable Handpiece Cable	GS807-RC (510k K090586)	GS807-RC (510k K090586)

510(k) SUMMARY

(As Required per 21 CFR 807.92(e))

DEVICE FUNCTION, TECHNOLOGY, AND INTENDED USE:

The Bovie® J-Plasma Handpiece with Retractable Cutting Tip are single use devices designed to be compatible only with the ICON GS generator (GS100) and reusable cable (GS-807-RC) cleared under 510k K-090586. There are device models for both open and laparoscopic surgical procedures (GS-018C and GS-270C respectively). These handpieces contain a programmable memory device that requires a unique code for the generator to operate. Each handpiece has a button for finger activation of the generator. Once activated, helium gas flows out the distal end of the device where gas molecules are excited by the high electric field resulting in a plasma stream. The handpiece that is intended for open procedures does not have an extended shaft. The handpiece intended for laparoscopic procedures has a 27 cm extended tip. Both handpieces contain a retractable cutting blade that can be extended manually for excising tissue.

INTENDED USE:

Plasma:

The Bovie® J-Plasma Handpiece with Retractable Cutting Blade is an electrosurgical device that utilizes helium gas plasma for coagulation of soft tissue during both open and laparoscopic surgical procedures.

Blade:

The Bovie® J-Plasma Handpiece with Retractable Cutting Blade is an electrosurgical device that utilizes a retractable blade for cutting of soft tissue during both open and laparoscopic surgical procedures.

ELECTRICAL STANDARDS:

Both named devices and the predicate are designed to comply with the following electrical standards:

- | | |
|----------------|---|
| IEC 60601-1: | Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety (2005) |
| IEC 60601-2-2: | Medical Electrical Equipment - Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories (2009) |

510(k) SUMMARY

(As Required per 21 CFR 807.92(c))

Characteristics	Bovie® J-Plasma Handpiece with Retractable Cutting Blade (This Submission)	Bovie® ICON GS Electro-surgical Handpiece (K-090586)
Indications for Use	<p>Plasma: The Bovie® J-Plasma Handpiece with Retractable Cutting Blade is an electro-surgical device that utilizes helium gas plasma for coagulation of soft tissue during both open and laparoscopic surgical procedures.</p> <p>Blade: The Bovie® J-Plasma Handpiece with Retractable Cutting Blade is an electro-surgical device that utilizes a retractable blade for cutting of soft tissue during both open and laparoscopic surgical procedures.</p>	An electro-surgical device that utilizes Helium gas for the coagulation of soft tissues during open soft tissue surgery.
Electrical Safety Standards	IEC60601-2-2, IEC60601-1	IEC60601-2-2, IEC60601-1
Output Energy Coagulation	40 Watts (100% Setting on ICON GS Generator)	40 Watts (100% Setting on ICON GS Generator)
Delivery System	Monopolar	Monopolar



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

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

JAN 27 2012

Re: K112233

Trade/Device Name: BOVIE® J-Plasma Handpiece with Retraceable Cutting Blade
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 19, 2012
Received: January 20, 2012

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.

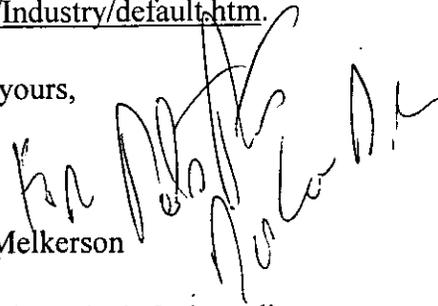
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Richard A. Kozloff

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: **Bovie® J-Plasma Handpiece with Retractable Cutting Blade**

Indications for Use:

The Bovie® J-Plasma Handpiece with Retractable Cutting Blade is an electrosurgical device that utilizes helium gas and a retractable blade for cutting and coagulation of soft tissue for use during both open and laparoscopic surgical procedures.

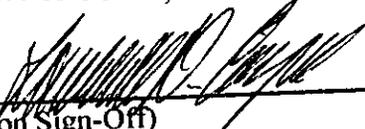
Prescription Use
(Part 21 CFR 801 Subpart D)

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)



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

510(k) Number K112233