



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Bovie Medical Corporation
Mr. Brian Kunst
Vice President, Quality Assurance/Regulatory Affairs
5115 Ulmerton Road
Clearwater, Florida 33760

August 4, 2015

Re: K151325

Trade/Device Name: Bovie J-Plasma Handpiece

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: May 15, 2015

Received: May 18, 2015

Dear Mr. Kunst:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151325

Device Name
Bovie J-Plasma Handpiece

Indications for Use (Describe)

The Bovie J-Plasma Handpiece is used for the delivery of helium gas plasma for cutting, coagulation, and ablation of soft tissue during open and laparoscopic surgical procedures.

The Bovie J-Plasma Handpiece is compatible only with Bovie J-Plasma generators.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

K151325

(Submitted As Required per 21 CFR 807.92)

GENERAL INFORMATION:

Submitter Name: Bovie Medical Corporation

Establishment Registration Number: 3007593903

Submitter Address: 5115 Ulmerton Road
Clearwater, Florida 33760-4004
United States of America

Submitter Telephone Number: (727) 803-8617

Submitter FAX Number: (727) 322-4465

Contact Person: Brian Kunst
Vice President, Regulatory Affairs and Quality Assurance

Date Prepared: May 15, 2015

DEVICE IDENTIFICATION:

Proprietary Name: **Bovie J-Plasma Handpiece**

Common Name: Electrosurgical Generator Accessory

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

Model Numbers: Multiple

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

Legally Marketed Predicate Device(s): 510(k) Number: K112233

Predicate Device Name: Bovie J-Plasma Handpiece
Manufacturer: Bovie Medical Corporation



510(k) SUMMARY

INTENDED USE/INDICATIONS

The Bovie J-Plasma Handpiece is used for the delivery of helium gas plasma for cutting, coagulation, and ablation of soft tissue during open and laparoscopic surgical procedures.

The Bovie J-Plasma Handpiece is compatible only with Bovie J-Plasma generators.

DEVICE DESCRIPTION

The **Bovie J-Plasma Handpiece** is a sterile, single use electrosurgical accessory intended to be used in conjunction with Bovie J-Plasma electrosurgical for the delivery of helium gas plasma for cutting, coagulating, and ablating soft tissue.

The **Bovie J-Plasma Handpiece** is available with a retractable cutting blade tip for excising tissue or a needle tip. Both tip configurations serve as electrodes to generate helium plasma. The device is available in 15cm, 33cm, and 45cm lengths. The device can be used in laparoscopic or open surgical procedures.



The primary differences between the proposed J-Plasma handpieces and predicate J-Plasma handpieces are:

- Pistol grip shape
- Available in 15cm, 33cm, and 45cm shaft lengths for open and laparoscopic procedures, compared to the predicate 18cm and 27cm lengths
- Available with blade or needle electrode instead of only blade electrode

There are no technological differences or changes to principle of operation. There are no changes to intended use, design, material, chemical composition, or energy source. Both devices require a Bovie J-Plasma generator and channel helium gas flow over an energized inner electrode to create a plasma stream.



510(k) SUMMARY

PERFORMANCE TESTING

Performance testing to assure that the Bovie J-Plasma Handpiece meets performance requirements was performed and is summarized in the following table:

Test	Objective	Protocols
Mechanical Verification and Functionality	Verify the mechanical functionality of the handpiece.	VR-1191 VR-1323
Electrical Verification	Verify the electrical functionality and safety of the handpiece.	VR-1191
Plasma Characteristics	Measure effect of generator settings on the plasma stream, plasma stream characterization	VR-1323
Performance Evaluation	Confirm device performance on various tissue types.	VR-1323
Usability Evaluation	The purpose of this protocol is to verify and validate the usability of the J-Plasma Pistol Grip Handpiece as it relates to safety.	VR-1216
Shipping Study	Verify the device meets requirements after shipping and handling.	VR-1191

The handpiece, and the predicate handpiece, was designed in accordance with the following standards:

International Standard	Description
IEC-60601-1, Edition 3.1	Medical Electrical Equipment - Part 1: General Requirements For Safety
IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC-60601-2-2 : 2009	Particular requirements for the safety of high frequency surgical equipment
ANSI / AAMI / ISO 10993-1:2009	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
ANSI/AAMI/ISO 11135-1: 2007	Sterilization of Healthcare Products – Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
ANSI / AAMI / ISO 10993-7:2008	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Residuals



510(k) SUMMARY

SUBSTANTIAL EQUIVALENCE

Feature/ Characteristic	Bovie J-Plasma Handpiece Current Submission	Bovie J-Plasma Handpiece (Predicate K112233)
Intended Use / Indications for Use	<p>The Bovie J-Plasma Handpiece is used for the delivery of helium gas plasma for cutting, coagulation, and ablation of soft tissue during open and laparoscopic surgical procedures.</p> <p>The Bovie J-Plasma Handpiece is compatible only with Bovie J-Plasma generators</p>	<p>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.</p>
Procedures	Open and Laparoscopic	Open and Laparoscopic
Energy Type	Helium gas plasma	Helium gas plasma
Output	Monopolar	Monopolar
User Interface	Pistol grip	Straight
Shaft Working Lengths	15cm, 33cm, 45cm	18cm, 27cm
Shaft Outer Diameter	5mm	5mm
Tip Configuration	Blade, Needle	Blade
Blade Extension	Maximum 10mm	Maximum 10mm
Blade Width x Thickness	0.4mm x 0.08mm	0.4mm x 0.08mm
Compatibility	Only with Bovie J-Plasma Generators	Only with Bovie J-Plasma Generators
Connector	Bovie Proprietary	Bovie Proprietary



CONCLUSION

The Bovie J-Plasma Handpiece has the same intended use, principle of operation, and utilizes the same technology as the predicate device. There is no new technology and no difference that would raise new or different questions of safety or efficacy. The differences between the subject device and the predicate device are mainly dimensional. Substantial equivalence was demonstrated through comparative bench testing.

Although there are slight difference in the wording of the indications statement between the subject device and the predicate device, the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and the differences do not affect the safety and effectiveness of the device when used as labeled. The devices are still used for the delivery of helium gas plasma for application on soft tissue during open and laparoscopic procedures.