DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 2, 2015

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

Re: K152570
Trade/Device Name: Bovie J-Plasma Precise 360 Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 4, 2015
Received: September 10, 2015

Dear Brian 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 Part 801 and Part 809); 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 . and Part 809), 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" (21 CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152570

Device Name
Bovie J-Plasma Precise 360 Handpiece

Indications for Use *(Describe)*

The Bovie J-Plasma Precise 360 Handpiece is used for the delivery of helium gas plasma for cutting, coagulation, and ablation of soft tissue during open and laparascopic surgical procedures.

The Bovie J-Plasma Precise 360 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 – K152570

(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 5115 Ulmerton Road Clearwater, Florida 33760-4004 United States of America
Contact email:	brian.kunst@boviemed.com
Date Prepared:	October 30, 2015

DEVICE IDENTIFICATION:

Proprietary Name:	**Bovie J-Plasma Precise 360 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: K151325

Predicate Device Name: Bovie J-Plasma Handpiece

Manufacturer: Bovie Medical Corporation

INTENDED USE/INDICATIONS

The Bovie J-Plasma Precise 360 Handpiece is used for the delivery of helium gas plasma for cutting, coagulation, and ablation of soft tissue during open and laparascopic surgical procedures.

The Bovie J-Plasma Precise 360 Handpiece is compatible only with Bovie J-Plasma generators.

DEVICE DESCRIPTION

The **Bovie J-Plasma Precise 360 Handpiece** is a sterile, single-use electrosurgical accessory intended to be used in conjunction with Bovie J-Plasma electrosurgical generators for the delivery of helium gas plasma for cutting, coagulating and ablating of soft tissue.

The **Bovie J-Plasma Precise 360 Handpiece** is available with a retractable needle tip, or with a retractable cutting blade tip for excising tissue. Both tip configurations serve as electrodes to generate helium plasma. A 30 degree angled shaft tip provides improved visibility during use, and a rotating knob is used to orient the angled shaft tip to the optimal position. The device is available with 33cm and 45cm shaft lengths. The device can be used in laparoscopic procedures using a standard 5mm trocar.

The primary differences between the proposed J-Plasma Precise 360 Handpiece and the predicate J-Plasma Handpiece are:

- The J-Plasma Precise 360 Handpiece is available in 33cm and 45cm shaft lengths and the predicate J-Plasma Handpiece is available in 15cm, 33cm, and 45cm shaft lengths
- The J-Plasma Precise 360 Handpiece has a rotating knob that controls an angled shaft tip which provides improved visibility and optimal positioning at the surgical site. The angled shaft tip uses a medical-grade which is not present in the predicate device. The rotating knob utilizes material which is present on the predicate device. The predicate J-Plasma Handpiece has a straight shaft tip.

The J-Plasma Precise 360 has the same intended use and energy source as the predicate device. There are no technological differences, no changes to the principle of operation or the method of application, and no changes to sterilization methods. Both devices require a Bovie J-Plasma electrosurgical generator and channel helium gas flow over an energized inner electrode to create a plasma stream.

PERFORMANCE TESTING

Performance testing to assure that the Bovie J-Plasma Precise 360 meets performance requirements was performed and is summarized in the following table:

Test	Objective	Reports
Mechanical Verification and Functionality	Verify the mechanical functionality of the device.	VR-1318 VR-1324
Electrical Verification	Verify the electrical functionality and safety of the device.	VR-1318
Plasma Characteristics	Measure effect of generator settings on the plasma stream, plasma stream characterization	VR-1324
Performance Evaluation	Confirm device performance on various tissue types.	VR-1324
Usability Evaluation	To verify and validate the usability of the J-Plasma Precise 360 as it relates to safety.	VP-1387
Shipping Study	Verify the device meets requirements after shipping and handling.	VP-1384
Evaluation of Rotation Effects	Evaluation of Shaft Rotation Effects on Plasma stream for Bovie J-Plasma Precise 360 Handpieces	VR-1383
Biocompatibility Testing	Verify material safety	VR-1335
Shelf Life Testing	Confirm product and package performance at labeled shelf life	VP-1326

The Bovie J-Plasma Precise 360 Handpiece, and the predicate Bovie J-Plasma Handpiece, were 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 Precise 360 Current Submission	Bovie J-Plasma Handpiece (Predicate K151325)
Intended Use / Indications for Use	The Bovie J-Plasma Precise 360 is used for the delivery of helium gas plasma for cutting, coagulation, and ablation of soft tissue during open and laparascopic surgical procedures. The Bovie J-Plasma Precise 360 is compatible only with Bovie J-Plasma generators.	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 laparascopic surgical procedures. The Bovie J-Plasma Handpiece is compatible only with Bovie J-Plasma generators.
Energy Type	Helium gas plasma	Helium gas plasma
Output	Monopolar	Monopolar
User Interface	Pistol grip	Pistol grip
Shaft Design	Angled	Straight
Shaft Rotation	Yes	No
Shaft Working Lengths	33cm and 45cm	15cm, 33cm, 45cm
Shaft Configuration	Angled	Straight
Shaft Outer Diameter	5mm	5mm
Tip Configuration	Blade, Needle	Blade, Needle
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

There is no difference between the J-Plasma Precise 360 Handpiece and the legally marketed predicate device Bovie J-Plasma handpiece described in K151325 in terms of intended use, principle of operation, and the technology used for device performance. All features of the Bovie J-Plasma Precise 360 were subjected to verification testing. There is no new technology and no difference that would raise new or different questions of safety or efficacy. The angled shaft tip and rotating knob components are mechanical in nature and do not affect the technology of the device. The purpose of the angled tip and rotating shaft is to allow better positioning of the tip and better visualization of the target tissue. The devices exhibit substantially equivalent performance during bench testing, including equivalent depth of tissue effect.