DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 8, 2017

Bovie Medical Corporation
Ms. Rubiela Maldonado
Regulatory Affairs Manager
5115 Ulmerton Road
Clearwater, Florida 33760

Re: K170188
Trade/Device Name: Bovie J-Plasma Precise Open Handpieces & Bovie Ultimate Gen 2 High Frequency 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: January 23, 2017
Received: January 24, 2017

Dear Ms. Maldonado:

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 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,

Jennifer R. Stevenson -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)*
K170188

Device Name
The Bovie Ultimate® Electrosurgical Generators, and Bovie J-Plasma Precise Open® Handpiece

Indications for Use *(Describe)*
The Bovie Ultimate® Electrosurgical Generators are indicated for delivery of radiofrequency energy and/or helium gas plasma to cut, coagulate and ablate soft tissue during open and laparascopic surgical procedures. The J-plasma portion of the generator can be used only with dedicated Bovie J-Plasma handpieces.

The Bovie J-Plasma Precise Open® Handpiece is intended to be used in conjunction with the Bovie Ultimate® electrosurgical generator for the delivery of radiofrequency energy and/or a helium gas plasma for electrosurgical cutting, coagulation and ablation of soft tissue during open surgical procedures. The Bovie J-Plasma Precise Open® Handpiece is compatible with Bovie Ultimate® Electrosurgical Generators BVX-200H, and BVX-200P.

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

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) 803-8508
Submitter FAX Number:	(727) 322-4465
Contact Person:	Rubiela Maldonado Regulatory Affairs Manager
Contact email:	Rubiela.Maldonado@boviemed.com
Date Prepared:	January 10, 2017

DEVICE IDENTIFICATION:

Proprietary Name:	**Bovie J-Plasma Precise Open® Handpiece & Bovie Ultimate® Gen 2 High Frequency Electrosurgical Generator**
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) Numbers: K112233, K151325, K152570 & K142975 Predicate Device Name: Bovie J-Plasma Handpiece & Bovie Ultimate High Frequency Electrosurgical Generator

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510(k) SUMMARY

INTENDED USE/INDICATIONS

The Bovie Ultimate® Electrosurgical Generators are indicated for delivery of radiofrequency energy and/or helium gas plasma to cut, coagulate and ablate soft tissue during open and laparascopic surgical procedures. The J-plasma portion of the generator can be used only with dedicated Bovie J-Plasma handpieces.

The Bovie J-Plasma Precise Open® Handpiece is intended to be used in conjunction with the Bovie Ultimate® electrosurgical generator for the delivery of radiofrequency energy and/or a helium gas plasma for electrosurgical cutting, coagulation and ablation of soft tissue during open surgical procedures. The Bovie J-Plasma Precise Open® Handpiece is compatible with Bovie Ultimate® Electrosurgical Generators BVX-200H, and BVX-200P.

BOVIE ULTIMATE GEN 2 ELECTROSURGICAL GENERATOR

DEVICE DESCRIPTION

Bovie Ultimate® Gen 2 Electrosurgical Generator is a multipurpose electrosurgical device that delivers high frequency electrical energy to cut and coagulate soft tissue. It can also deliver Helium gas plasma energy (J-Plasma) for the cutting, coagulation, and ablation of soft tissue.

The Ultimate Gen 2 electrosurgical generator is the next generation of the original Bovie Ultimate®. The Ultimate Gen 2 has offers the same electrosurgical modes and has the same performance specifications as the original Bovie Ultimate, but the Ultimate Gen 2 will be compatible with the new Bovie J-Plasma Precise Open handpiece passive accessory.

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Figure 1. Ultimate Gen 2 BVX-200H

Ultimate electrosurgical generators features two (2) cut modes up to 300 watts, three (3) blend modes, three (3) coagulation modes, three (3) bipolar modes and J-plasma mode adjustable up to 40W power (100%) and 1-5 LPM helium gas flow. The generator offers one (1) monopolar handpiece output, one (1) monopolar foot controlled output, one (1) bipolar handpiece output, one (1) bipolar foot controlled output, and one J Plasma (helium) gas outlet.

The generator is designed to comply with applicable Medical Electrical Equipment safety standards, and is designed to meet the requirements of the European Restriction of Hazardous Substances Directive (2011/65/EU) directive.

BOVIE J-PLASMA PRECISE OPEN HANDPIECE

DEVICE DESCRIPTION

The **Bovie J-Plasma Precise Open Handpiece** is a sterile, single use electrosurgical accessory intended to be used in conjunction with the **Bovie Ultimate Gen 2** electrosurgical generator for the delivery of radiofrequency energy and/or a helium plasma gas for electrosurgical cutting, coagulation and ablation of soft tissue during open surgical procedures. The handpiece utilizes a retractable blade or needle electrode to ignite the helium gas to create the plasma.

The **Bovie J-Plasma Precise Open handpiece** represents an enhancement of the original Bovie J-Plasma Handpiece:

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- Ergonomic shape
- Lighter, due to removal of internal transformer
- Has 2 buttons to select either standard monopolar coagulation or J-Plasma. Original handpiece has only one button for activation of J-Plasma.
- The shaft on the new **Bovie J-Plasma Precise Open Handpiece** with blade electrode can be rotated which can be used rotate the blade. This enables the user to place the blade in the desired orientation.

Figure 1. Bovie J-Plasma Precise Open Handpiece

There are no technological differences or changes to principle of operation. An additional button on the device gives the user the ability to use the monopolar coagulation mode on the Bovie Ultimate Electrosurgical Generator.

There are no changes to the principle of operation or the method of application, and no changes to sterilization methods.

PERFORMANCE TESTING

Performance testing to assure that the Bovie J-Plasma Precise Open Handpiece and the Ultimate Gen 2 meet performance requirements were performed and are summarized in the following tables:

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Test	Objective	Protocols
Mechanical Verification and Functionality	Verify the mechanical functionality of the handpiece	VR-1476 VR-1496
Electrical Verification	Verify the electrical functionality and safety of the handpiece	VR-1476
Electrical Verification	Verify the electrical functionality and safety of the Ultimate Gen 2 Generator.	VR-1610031
Inspectional Verification	Document parameters that can be verified through inspection for the Ultimate Gen 2 generator.	VR-1610032
Plasma Characteristics	Measure effect of generator settings on the plasma stream, plasma stream characterization	VR-1496
FPGA Validation for the Main Board	Perform testing required to verify Main Board FPGA.	VR-1491
FPGA Validation for the Display Board	Perform testing required to verify Display Board FPGA.	VR-1490
Performance Evaluation	Confirm device performance on various tissue types	VR-1496

BOVIE ULTIMATE GEN 2 ELECTROSURGICAL GENERATOR SUBSTANTIAL EQUIVALENCE

Feature/ Characteristic	Bovie Ultimate Gen 2 Electrosurgical Generator (This Submission)	Bovie Ultimate Electrosurgical Generator (Predicate device 510(k) K142975
Intended Use / Indications for Use	The Bovie Ultimate® Electrosurgical Generators are indicated for delivery of radiofrequency energy and/or helium gas plasma to cut, coagulate and ablate soft tissue during open and laparascopic surgical procedures. The J-plasma portion of the generator can be used only with dedicated Bovie J-Plasma handpieces.	The Bovie Ultimate Electrosurgical Generators are 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 Ultimate generators.

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510(k) SUMMARY

Feature/ Characteristic	Bovie Ultimate Gen 2 Electrosurgical Generator (This Submission)	Bovie Ultimate Electrosurgical Generator (Predicate device 510(k) K142975
Technology / Energy Used, Delivered	Uses High Frequency Radiofrequency (RF) energy to create clinical effect. The electrical properties of the waveform (frequency, peak, and duration) produce the clinical effect (i.e. coagulation and cutting). For soft tissue coagulation using Helium gas, the flow rate produces clinical effect (i.e. coagulation and ablation).	Uses High Frequency Radiofrequency (RF) energy to create clinical effect. The electrical properties of the waveform (frequency, peak, and duration) produce the clinical effect (i.e. coagulation and cutting). For soft tissue coagulation using Helium gas, the flow rate produces clinical effect (i.e. coagulation and ablation).
User Interface	Push buttons, Seven segment display and LEDs.	Push buttons, Seven segment display and LEDs.
Available Modes	Cut (2), Blend (3), Coagulation (3: pinpoint, spray, gentle), Bipolar (3: Macro, Micro, Standard), and J-Plasma (2 -with Active accessory and with Passive accessory)	Cut (2), Blend (3), Coagulation (3: pinpoint, spray, gentle), Bipolar (3: Macro, Micro, Standard), and J-Plasma (1)
Electrical Safety Standards/ Compatibility with Other Devices	Complies with IEC60601-1 (third edition), IEC60601-2(electromagnetic compatibility), and IEC60601-2-2 standard for the safety of electrosurgical equipment.	Complies with IEC60601-1 (third edition), IEC60601-2(electromagnetic compatibility), and IEC60601-2-2 standard for the safety of electrosurgical equipment.

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Feature/Characteristic		Bovie Ultimate Gen 2 Electrosurgical Generator (This Submission)	Bovie Ultimate Electrosurgical Generator (Predicate device 510(k) K142975
Product Dimensions	Length	14.75"	14.75"
	Depth	18.1"	18.1"
	Height	6.5"	6.5"
	Weight	20lbs.	20lbs.
Power Input	Mains Frequency	50-60Hz	50-60Hz
	Mains Voltage	100-240VAC +/- 10%	100-240VAC +/- 10%
	Maximum Power Consumption	650VA	504 VA

BOVIE J-PLASMA PRECISE OPEN HANDPIECE SUBSTANTIAL EQUIVALENCE

Feature/ Characteristic	Bovie J-Plasma Precise Open Handpiece	Bovie J-Plasma Handpiece (Predicate K112233, K151325, K152570)
Intended Use / Indications for Use	The Bovie J-Plasma Precise Open® Handpiece is intended to be used in conjunction with the Bovie Ultimate® electrosurgical generator for the delivery of radiofrequency energy and/or a helium gas plasma for electrosurgical cutting, coagulation and ablation of soft tissue during open surgical procedures. The Bovie J-Plasma Precise Open® Handpiece is compatible with Bovie Ultimate® Electrosurgical Generators BVX-200H, and BVX-200P.	K112233- 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. K151325, K152570- The Bovie J-Plasma Precise Open® Handpiece is used for the delivery of helium gas plasma for cutting, coagulation, and ablation of soft tissue during open surgical procedures. The Bovie J-Plasma Handpiece is compatible only with Bovie

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		Ultimate Generators.
Procedures	Open	Open and Laparascopic
Energy Type	Helium gas plasma	Helium gas plasma
Output	Monopolar	Monopolar
User Interface	Straight	Straight
Shaft Working Lengths	44mm, 150mm	18mm, 150mm, 270mm 330mm, 450mm
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 Ultimate Gen 2 Generators	Only with Bovie Ultimate Generators
Connector	Bovie Proprietary	Bovie Proprietary

CONCLUSION

The Bovie Ultimate® Gen 2 Electrosurgical Generator has the same intended use, principles of operation, and utilizes the same technology as the predicate device. The Bovie Ultimate Gen 2 Electrosurgical Generator provides standard electrosurgical energy and J-Plasma energy, the same as the original Bovie Ultimate Generator.

There are no changes to the performance specifications, electrosurgical modes, or maximum power settings of the new generator compared to the original. When connected to an active handpiece accessory, the Bovie Ultimate Gen 2 performs identically to the original Ultimate. The primary difference between the Ultimate Gen 2 and the original Ultimate is that the Ultimate Gen 2 offers compatibility with a J-Plasma passive handpiece accessory. This involves supplying standard monopolar coagulation energy to the J-Plasma handpiece connection and providing a passive J-Plasma mode. The Ultimate Gen 2 is compatible with both active and passive accessories.

The Bovie J-Plasma Precise Open Handpiece is intended for cutting, coagulation, and ablation of soft tissue. The Bovie J-Plasma Precise Open Handpiece 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.

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The differences between the predicate and subject handpieces are related to the shape, the removal of the transformer to reduce weight for easier handling, and the addition of a coagulation button on the handpiece to give the user the ability to use coagulation mode on the Bovie Ultimate Electrosurgical generator without having to switch to a secondary electrode handpiece. The new handpiece also offers the ability to rotate the blade electrode for optimal positioning.

The Bovie J-Plasma Precise® Open Handpiece and Ultimate Gen 2 were subjected to verification testing that confirmed device performance and demonstrated equivalent tissue effect between the J-Plasma passive accessory and active accessory. There is no new technology or any differences that would raise new or different questions of safety or efficacy.