DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 29, 2016

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

Re: K161558
Trade/Device Name: Bovie 3.3mm Disposable Bipolar Ablator 90º , Aspirating and Non-aspirating;
Bovie 2.4mm Disposable Bipolar Ablator 55º , Non-aspirating;
Bovie 1.8mm Disposable Bipolar Ablator 60º , Non-aspirating.
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 3, 2016
Received: June 6, 2016

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 yours,

Christopher J. Ronk -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)*

K161558

Device Name

Bovie Disposable Bipolar Ablator

Indications for Use *(Describe)*

This device is intended to be used for cutting, vaporization, and coagulation of soft tissue during arthroscopic surgical procedures. This device is intended to be used with a standard electrosurgical generator with footswitch control and a standard return electrode connection, and the electrode is to be activated only when immersed in a conductive media such as standard saline solution.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Bovie

510(k) SUMMARY

(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) 803-8508
Submitter FAX Number:	(727) 322-4465
Contact Person:	Rubiela Maldonado Regulatory Affairs Manager
Date Prepared:	July 26, 2016

DEVICE IDENTIFICATION:

Proprietary Name:	**Bovie Disposable Bipolar Ablator**
Common Name:	Electrosurgical Generator Accessory
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories

Model Numbers:

Catalog #	Description
BA3390A	3.3mm Disposable Bipolar Ablator 90°, Aspirating
BA3390NA	3.3mm Disposable Bipolar Ablator 90°, Non-Aspirating
BA2455NA	2.4mm Disposable Bipolar Ablator 55°, Non-Aspirating
BA1860NA	1.8mm Disposable Bipolar Ablator 60°, Non-Aspirating

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

Legally Marketed Predicate Device(s):

- K120791, K083306 ArthroCare SuperTurbo Vac 90, TurboVac 90, Arthrocare ArthroWand® 2.3mm 35° Short Bevel and Microblator 30 With Integrated Cable
- K152777 Bovie Disposable Bipolar Ablator

INTENDED USE/INDICATIONS

This device is intended to be used for cutting, vaporization, and coagulation of soft tissue during arthroscopic surgical procedures. This device is intended to be used with a standard electrosurgical generator with footswitch control and a standard return electrode connection, and the electrode is to be activated only when immersed in a conductive media such as standard saline solution.

DEVICE DESCRIPTION

The device is comprised of the following major components: an insulated handle, an active electrode, a length of aspiration tubing, a standard foot-switch RF connector, and a standard return connector. The hand piece is designed to connect to electrosurgical generators that feature a standard foot switch controlled monopolar connector and a standard return connector.

A stainless steel electrode tip is surrounded by a ceramic thermal insulator. The product is available in shaft diameters of 3.3mm, 2.4mm, and 1.8mm. The larger size is available in aspirating and non-aspirating version. The aspirating versions use suction to remove saline irrigant during the surgical procedure for the dissipation of heat and improved vision.

The device is available in electrode face angles of 55 degrees, 60 degrees, and 90 degrees. There is a feature on the handle that lets the operator easily determine the orientation of the active electrode face. The wedge-shaped tapered tip allows access to difficult to reach locations. The working length is 160mm. The cable from the handle is 126” +/- 6” in length.

The device operates in bipolar mode. The return electrode is located on the device and does not require the use of an external grounding pad or return electrode. The device has a simple user interface that uses a footswitch to activate the device.

The Bovie Disposable Bipolar Ablator has the same intended use and energy type as the predicate device. There are no technological differences, no changes to the principle of operation or the method of application.

PERFORMANCE TESTING

Performance testing was completed to demonstrate substantial equivalence of the subject device to the predicates. The devices were subjected to the following verification and validation tests, as applicable:

Mechanical testing

Mechanical verification testing was conducted for the proposed device to ensure compliance with mechanical requirements of IEC-60601-1, Edition 3.1, IEC 60601-2-2: 2009, and Bovie self-enforced requirements.

Electrical testing

Electrical verification testing was conducted for the relevant components of the proposed device to ensure compliance with current electrical standard requirements.

Electromagnetic compatibility

Electromagnetic compatibility (EMC) testing has been completed for the applicable components of the proposed device. The results demonstrated compliance of the proposed device to current IEC 60601-1-2 standard requirements.

Biocompatibility

Biocompatibility verification was performed in accordance with requirements of ISO 10993-1 and FDA's modified ISO guidelines in accordance with FDA's blue book memorandum #G95-1 on biocompatibility.

INE Testing

Testing was conducted to demonstrate that the Bovie Disposable Bipolar RF Arthroscopy Ablator is able to withstand the insertion / navigation / extraction actions during a procedure.

Bench-top validation testing

- Visual Inspection & Electrical Continuity Testing:
  Testing was conducted to: Meet general workmanship requirement. Pass electrical continuity test.
- Mold Stress Relief Testing:
  Testing was conducted to demonstrate: Any shrinkage or distortion of the molded thermoplastic components due to release of internal stresses caused by the molding operation does not result in an unacceptable risk.
- Cable Strain (steady pull) Relief Testing:
  Testing was conducted to demonstrate: The ablator cable and its connections are capable of withstanding mechanical stress from a steady pull
- Cable Impulse Testing and Post-impulse continuity testing:
  Testing was conducted to demonstrate: The ablator cable and its connections are capable of withstanding mechanical stress from an impulse of force.
- Cable Flexure / Tension and Post-Flexure-testing Electrical Continuity Testing:
  Testing was conducted to: Evaluate the integrity of the anchorage (fastening, termination) of electrical conductors and insulation by exercising the cable / cords by flexing and applying specified tension.
- Drop Testing:
  Testing was conducted to: Verify the ablator will not present a safety hazard as a result of a free fall onto a hard surface.
- Front Panel Connection Verification Testing:

Testing was conducted to: Verify that Proximal End (brass sockets) of the ablator cable connects to a compatible generator.

- Connector Insertion / Extraction Force Testing:
  Testing was conducted to: Verify that the insertion / Extraction force for inserting / extracting ablator cable connector into or from a compatible generator is within specified range.
- Measurement and Maximum Temperature During Use (Aspirating Model):
  Testing was conducted to: Assess the maximum temperature that ablator handle can achieve during a worst case use scenario
- Measurement and Maximum Temperature During Use (Non-Aspirating Model):
  Testing was conducted to: Assess the maximum temperature that ablator handle can achieve during a worst case use scenario
- Rigidity Testing of Handle and Shaft:
  Testing was conducted to: Verify that handle of an ablator is able to support a static weight located at the distal position on the shaft without permanently deforming
- Compatibility Verification Testing:
  Testing was conducted to: Verify that the ablator is able to function as intended when connected to a compatible electrosurgical generators.
- Aspiration Flow Testing:
  Testing was conducted to: Verify aspiration flow rate under specific vacuum conditions.
- Thermal Performance & clogging Testing:
  Testing was conducted to: Verify the performance of the Bovie Disposable Bipolar RF Arthroscopic Ablator in terms of 1) thermal performance (the temperature of irrigation fluid near the active electrode during activation of a device); 2) tissue removal, 3) clogging, and 4) ignition delay
- Thermal Performance Testing (Non-Aspirating ablator):
  Testing was conducted to: Assess the fluid temperature near the active electrode during activation of an ablator. The electrosurgical generator is to be set at the maximum allowable power for ablator model in order to simulate the worst case scenario.

All test requirements were met as specified by applicable standards and the test protocols.

The Bovie Disposable Bipolar Ablator 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

Bovie

SUBSTANTIAL EQUIVALENCE SUMMARY

Feature/ Characteristic	Bovie Disposable Bipolar Ablator	ArthroCare SuperTurbo Vac, Turbovac 90 Arthrocare ArthroWand® 2.3mm 35° Short Bevel Arthrocare ArthroWand® Microblator 30 With Integrated Cable	Bovie Disposable Bipolar Ablator BA3350NA, BA3350A
Intended Use	Intended to be used for cutting, vaporization, and coagulation of soft tissue during arthroscopic surgical procedures.	Intended to be used for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures.	Intended to be used for cutting, vaporization, and coagulation of soft tissue during arthroscopic surgical procedures.
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency
Generator Compatibility	To be used with a standard electrosurgical generator with footswitch control and a standard return electrode connection	Dedicated generator	To be used with a standard electrosurgical generator with footswitch control and a standard return electrode connection
Use only in Conductive Media	The electrode is to be activated only when immersed in a conductive media such as standard saline solution	Same	The electrode is to be activated only when immersed in a conductive media such as standard saline solution
Mode	Bipolar	Bipolar	Bipolar
User Interface	Footswitch	Footswitch and Hand	Footswitch
Aspirating and Non-Aspirating Models	Yes	Yes	Yes
Shaft Diameter	3.3mm, 2.4mm, 1.8mm	3.75mm 2.3mm and 1.4mm	3.3mm
Electrode Face Angle	90, 55, 60 degrees	90,35, 30 degrees	50 degrees
Working Length	160mm	160mm	160mm

CONCLUSION

In summary, the only differences between the subject and the predicate devices are:

- Generator compability
- user interface
- Shaft diameter
- Electrode Face angle

These differences between the Bovie Disposable Bipolar Ablator and the predicate devices do not raise new or different questions of safety and efficacy. The Bovie Disposable Bipolar Ablator was subjected to verification testing to confirm device performance. There is no new technology and no difference that would raise new or different questions of safety or efficacy. Comparative performance testing demonstrated the device performed as well as, or better than, the predicate device.

There is no difference between the Bovie Disposable Bipolar Ablator and the predicate devices in terms of intended use, principle of operation, and the technology used for device performance.