



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

June 20, 2016

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

Re: K161134

Trade/Device Name: Bovie Bantam/Pro, Bovie Derm 941, Bovie Derm 942 Electrosurgical Generators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 15, 2016
Received: April 22, 2016

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 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,

Jennifer R. Stevenson -A

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)

K161134

Device Name

Bovie Bantam/PRO Electrosurgical Generator, DERM 942 Electrosurgical Generator, DERM 941 Electrosurgical Generator

Indications for Use (Describe)

The intended use for the DERM 941 and DERM 942 is for removal and destruction of skin lesions and the coagulation of tissue.

The intended use for the Bantam/PRO is for removal and destruction of skin lesions and for electrosurgical cutting, blending, coagulation, fulguration, and bipolar procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



510(k) SUMMARY
K161134

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: June 15, 2016

DEVICE IDENTIFICATION:

Proprietary Names: **Bantam/PRO Electrosurgical Generator**
DERM 942 Electrosurgical Generator
DERM 941 Electrosurgical Generator

Common Name: Electrosurgical Generator

Classification Name: 21CFR 878.4400; Class II; Product Code GEI
Electrosurgical Cutting and Coagulation Device and
Accessories

Model Numbers:

| Catalog # | Description |
|-----------|--------------------------------------|
| A952 | Bantam/PRO Electrosurgical Generator |
| A942 | DERM 942 Electrosurgical Generator |
| A 941 | DERM 941 Electrosurgical Generator |



510(k) SUMMARY

K161134

**Legally Marketed
Predicate Device(s):**

K021817: Aaron A950 Electrosurgical Generator
Manufacturer: Bovie Medical Corporation
K000961: Aaron A900 Electrosurgical Generator
Manufacturer: Bovie Medical Corporation
K134054: Bovie IDS-310 Electrosurgical Generator
Manufacturer: Bovie Medical Corporation

INTENDED USE/INDICATIONS

The intended use for the DERM 941 and DERM 942 is for removal and destruction of skin lesions and the coagulation of tissue.

The intended use for the Bantam/PRO is for removal and destruction of skin lesions and for electrosurgical cutting, blending, coagulation, fulguration, and bipolar procedures.

DEVICE DESCRIPTION

The Bantam/PRO performs the following functions:

Cut mode: Allows the user to utilize electrosurgical current to vaporize or cut tissue.

Blend mode: Combines cutting with hemostasis, which achieves a bloodless cut.

Coagulation mode: Is used for the destruction of tissue and hemostasis.

Fulguration mode: Allows the user to coagulate over a broad area with less tissue penetration.

Bipolar mode: Allows coagulation of tissue using forceps.

The DERM 942 has the following functions shared with the Bantam/PRO:

Fulguration mode: Allows the user to coagulate over a broad area with less tissue penetration.

Bipolar mode: Allows coagulation of tissue using forceps.

The DERM 941 has only the basic **Fulguration** mode function.



510(k) SUMMARY
K161134

The DERM 942 and 941 are termed High Frequency Dessicators since they perform treatment of skin lesions. The fulguration and bipolar are termed the dessication modes. The Bantam/PRO performs treatment of skin lesions but also has the basic cut and coagulation functions of a typical electrosurgical generator. All these units are considered low wattage (<50W).

PERFORMANCE TESTING

Performance testing was completed to demonstrate substantial equivalence of the subject device to the predicate (K120791). The devices were subjected to the following verification and validation tests, as applicable:

| Test Category / Protocol Number | Purpose | Verification Performed |
|--|---|--|
| Electrical Verification | To verify electrical product and performance specification requirements where the test method is other than inspection or proof by design evidence. | Perform testing required to verify the electrical functionality of the generator. |
| FPGA Validation for Main Board | To specify the FPGA validation procedure for the logic design used in the generator. | Validate the operation of the programmable systems on the main board of the generator to ensure FPGA design meets functional and timing requirements. |
| Mechanical Verification | To verify mechanical product and performance specification requirements | Perform testing required to verify the mechanical functionality of the generator and to ensure generator has adequate mechanical strength and resistance to heat |
| Usability Validation | Validate the user interface of the Electrosurgical Generator. | Validate that the device fulfills the user needs and intended uses |



510(k) SUMMARY
K161134

The Bovie Bantam/PRO, DERM 942, and DERM 941 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 |



510(k) SUMMARY
K161134

SUBSTANTIAL EQUIVALENCE SUMMARY

| | Bovie-Medical A900 Bovie Medical A950 Bovie-Medical IDS-310 | A952 Electrosurgical Unit | DERM 942 Electrosurgical Unit DERM 941 Electrosurgical Unit |
|--------------------------------|--|---|--|
| <i>Clinical</i> | | | |
| Intended Use | <p>A950- intended to be used for cutting and coagulation, fulguration, and bipolar procedures.</p> <p>A900: Intended for the removal and destruction of skin lesions and coagulation of tissue</p> | Intended for cutting and coagulation of soft tissue and removal and destruction of skin lesions | Intended for the removal and destruction of skin lesions and coagulation of tissue |
| <i>Technical</i> | | | |
| Source of Power | 100-240V AC 50/60Hz | 100-240V AC 50/60Hz | 100-240V AC 50/60Hz |
| Operating Principle | RF energy | RF energy | RF energy |
| Monopolar Output Type | A950: Isolated, floating - CUT, BLEND, COAGULATION Ground-referenced FULGURATION | A952: Isolated, floating - CUT, BLEND, COAGULATION Ground-referenced FULGURATION | DERM942/941 Ground-referenced FULGURATION |
| Power Regulation | Dial Knob and handle up/dn buttons | Dial Knob and handle up/dn buttons | Dial Knob and handle up/dn buttons |
| Maximum Output Power and Modes | A950 60W Monopolar Mode- Cut, Blend, Coagulation | 50W Monopolar Mode- Cut, Blend, Coagulation | Cut, Blend, Coagulation Modes not available |
| | A950 35W Fulguration A900 30W Fulguration | 40W Fulguration | 40W Fulguration |
| | A950 30W Bipolar mode A900 30W Bipolar mode | 40W Bipolar mode | DERM942 40W Bipolar mode |
| | IDS-310 50W Micro Bipolar mode | 40W Micro Bipolar Mode | Micro Bipolar mode not available |



510(k) SUMMARY
K161134

| | | | |
|--|--|--|--|
| | Bovie-Medical A900 Bovie Medical A950 Bovie-Medical IDS-310 | A952 Electrosurgical Unit | DERM 942 Electrosurgical Unit DERM 941 Electrosurgical Unit |
| Neutral Electrode Monitoring of Ground Pad | A950 – No IDS-310 - Yes | Yes | No |
| Ground Pad Type | A950 – Solid IDS-310 – Solid or Split | Solid or Split | Solid |

Accessories

| | | | |
|------------------|--------------------|--------------------|--------------------|
| Monopolar Handle | Bovie-Medical A901 | Bovie-Medical A902 | Bovie-Medical A902 |
| Accessory Kit | A900, A950 – Yes | Yes | Yes |

2.4 Enclosure

| | | | |
|--------------------|---|---|---|
| | <p>A950</p>  <p>A900</p>  | <p>A952</p>  | <p>DERM942</p>  <p>DERM941</p>  |
| IEC Classification | Class I | Class I | Class I |



510(k) SUMMARY
K161134

CONCLUSION

These generators are essentially a facelift and modernization of low powered generators that have been in Bovie's line for years. There is no difference between the new and the predicate devices in terms of intended use, technology, and features. All the features of the Bantam/PRO, DERM 942, and DERM 941 are present on the predicate devices. The Bantam/PRO incorporates the safety feature of return electrode monitoring which is a feature not available in the Aaron 950. There is no new technology and no difference that would raise new or different questions of safety or efficacy. Performance testing demonstrates equivalence between the proposed and predicate devices.