



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

Bios S.R.L.
Riccardo Pisati
Regulatory Affairs
Via Guido Rossa, 10/12
Vimodrone I-20090
Milan, Italy

November 19, 2015

Re: K151296

Trade/Device Name: Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: PBX

Dated: May 13, 2015

Received: May 15, 2015

Dear Mr. Pisati,

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 Parts 801 and 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), 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)
not assigned K151296

Device Name
Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250)

Indications for Use (Describe)

The Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

The Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) massage device is intended to provide a temporary reduction in the appearance of cellulite.

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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Section 5 510(k) Summary

Contact Details

510(K) Number K151296
Applicant Information Bios s.r.l.
Via Guido Rossa, 10/12
20090 Vimodrone (MI) – Italy
Contact Ing. Aldo Casalino
Date Prepared 13 May 2015
Device Name(s): Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250)
Trade Name Family of Radiofrequency System
Common Name Radiofrequency System
Classification II
Classification Name Electrosurgical, cutting and coagulation and accessories 21CFR 878.4400
Product Code PBX

Legally Marketed Predicate Device (s)

510(k) Number	Pro Code	Trade Name	Applicant
K133739	PBX 21 CFR 878.4400	TruSculpt	Cutera, Incorporated
K132949	PBX 21 CFR 878.4400	Pellefirm System	Ellman International, Inc

Device Description

The Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) is a medical electrical equipment for the development of localized heat that can heat the subcutaneous tissue with radio frequency. Its particular emission frequency of 470 kHz \pm 10%, the ability to regulate and control the increase of the desired temperature allows to operate with a maximum temperature of 45 ° C, and never exceed 47 ° C (for safety). The electrodes dimensions included, allow to obtain a controlled heating.

Indication for Use

The Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

The Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) massage device is intended to provide a temporary reduction in the appearance of cellulite.

Substantial Equivalence

The product specification, functionality, indication for use, and treatment parameters of the Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) are the same or very similar to the legally marketed, claimed predicate devices for the purpose of this 510(k) submission.

Technological differences between the Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) and the predicate devices are limited to small variations in the maximum power (250 W, while predicate devices have a range from 120 W to 300 W), display (touchscreen, while one predicate device uses an analogic system) and temperature control (one predicate device does not have it).

Performance Testing

The Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) has been tested and is in compliance with EN 60601-1, Medical electrical equipment. Part 1: General requirements for basic safety and essential performance 2006/A11:2010/A1:2013, EN60601-1-2 Medical electrical equipment. Part1: General requirements for safety – Collateral standard: Electromagnetic Compatibility – Requirements and tests. 2007 and EN 60601-2-2 Medical electrical equipment. Part 2-2: Particular requirements for the safety of high frequency surgical equipment. 2009.

In addition to the electrical safety testing performed, software verification and validation was conducted to FDA regulations, standards and guidance document requirements. The results of this testing conclude the software has met these requirements. Design verification and validation was also performed on the Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) in compliance with internal design control procedures. The results of this testing concludes the Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) is determined to be safe and effective and is substantially equivalent to the predicate devices.

Clinical Performance Protocol was performed to support use of the medical device, in particular the tests demonstrate that the device can heat the skin to 40-45 degrees C and can maintain the skin temperature inside that interval for 10 minutes similar to a heating lamp.