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510(k) Summary - K082391

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:
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Date Prepared: August 24, 2009

Trade Name: Primaeva Medical Miratone System

Common Name: Electrosurgical unit and accessories

Classification: Class II per 21 CFR 878.4400 – Electrosurgical cutting and coagulation device and accessories

Product Code: GEI

Predicate Devices: Primaeva Medical Finesse System – K072261
Primaeva Medical System – K080145

Device Description: The Primaeva Medical Miratone System is comprised of the following components: A reusable radiofrequency (RF) generator with user interface; a reusable cooler controller;

Serendia, LLC
Exhibit 2153
EndyMed v. Serendia
IPR2024-00844
Ex. 2153-001

a reusable cooler handpiece/applicator; a reusable electrode insertion device/applicator; and a single patient use, disposable electrode cartridge. RF energy is delivered from the RF generator through the electrodes into the target tissue.

Intended Use: The Primaeva Medical Miratone System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles.

Technological Characteristics Comparison: The Primaeva Medical Miratone System with indications for the percutaneous treatment of facial wrinkles is identical to the predicate Primaeva Medical System noted above.
The Primaeva Medical Miratone System with indications for the percutaneous treatment of facial wrinkles is considered to be substantially equivalent in terms of the target population, energy source, principles of operation, etc., to the above noted predicate devices.

Performance Data: Non-clinical testing of the Primaeva Medical Miratone System included visual and , mechanical inspection, electrical and mechanical safety testing, functional performance testing, etc., in bench and/or animal testing.
Clinical performance testing demonstrated the Primaeva Medical Miratone System to be safe and effective in the percutaneous treatment of facial wrinkles.

Summary: In summary, the results of non-clinical mechanical, electrical and functional bench and/or animal testing, and clinical performance testing have demonstrated that the Primaeva Medical Miratone System meets established design specifications; functions as intended; and is considered to be substantially equivalent to the above noted predicate devices.

- End of section -

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Primāeva Medical, Inc.
% Mr. Brian Grigsby
Vice President, QA & RA
4160 Hacienda Drive, Suite 100
Pleasanton, California 94588

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Re: K082391
Trade/Device Name: Primaeva Medical Miratone System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 30, 2009
Received: July 2, 2009

Dear Mr. Grigsby:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082391

Device Name: Primaeva Medical Miratone System

Indications for Use:

The Primaeva Medical Miratone System is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082391

End of section