K121481

JUN 2 5 2013

510(k) Summary for the
Lutronic Corporation INFINI Radiofrequency System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

General Information

Submitter:	Lutronic Corporation 219 Sowon-ro, Haengsin-dong, Deogyang-gu, Goyang-si, Gyeonggi-do, 410-722 Republic of Korea
Contact Person	Jhung Won Vojir, Ph.D. Global Regulatory Officer Lutronic, Inc. Six Neshaminy Interplex, Suite 100 Trevose, PA 19053 jvojir@lutronic.com Tele: 215-205-2219 FAX: 609-488-6958
Summary Preparation Date:	June 11, 2013

Names

Trade Name:	INFINI Radiofrequency System
Classification Name:	Electrosurgical, cutting & coagulation device & accessories Product Code: GEI Panel: General and Plastic Surgery

Predicate Devices

The INFINI Radiofrequency System is substantially equivalent to the Primaeva Medical Miratone System (K082391).

Device Description

The INFINI Radiofrequency System includes the system main body, a handpiece equipped with disposable handpiece tips, footswitch, and an LCD touch screen control panel. The RF energy is delivered using disposable handpiece tip. The radiofrequency energy is delivered to the target tissue using a handpiece and

disposable tip, the tip being placed in light contact with the epidermis, and the handpiece being held at right angles to the target tissue. As the RF energy passes through the skin, it generates an electro thermal reaction, which is capable of coagulating the tissue. Using the MFR tip (Microneedle Fractional RF) the INFINI Radiofrequency System creates heat within the target dermal tissue via microneedles inserted from the MFR tip.

Intended Use

The INFINI Radiofrequency System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles.

Technological Characteristics

The INFINI Radiofrequency System is substantially equivalent to the predicate device in technological characteristics, such as intended use, principles of operation, target population, and energy source. The INFINI Radiofrequency System and the predicate device are both bipolar radiofrequency systems, with delivery methods through optical fibers and handpieces. Both the INFINI Radiofrequency System and the predicate system are minimally invasive radiofrequency devices employing bipolar microneedle electrode systems.

Performance Data:

Non-clinical tests of the INFINI Radiofrequency System included bench testing, histology, electrical and mechanical safety testing. Using an *in vivo* micropig model, it was demonstrated that the INFINI Radiofrequency System delivered radiofrequency energy at a depth in the dermis without causing any electrothermal damage to the epidermis. Clinical trials, conducted in two study centers, established the substantial equivalence of the INFINI Radiofreqency System to the predicate device for the percutaneous treatment of facial wrinkles. Histologically, the controlled creation of dermally located thermal coagulation zones by the INFINI System was shown to be substantially equivalent to the thermal coagulation zones by the predicate device. Therefore, non-clinical and clinical tests established the substantial equivalence of INFINI Radiofrequency System to the predicate device, Primaeva Medical Miratone System (K082391).

Summary:

The intended use of the INFINI Radiofrequency System is virtually identical to the intended use of the predicate devices and the technological characteristics of the INFINI Radiofrequency System are similar to the technological characteristics of the predicate device. Any differences between the INFINI Radiofrequency System and the predicate device have no significant influence on safety or effectiveness of the INFINI Radiofrequency System. Therefore, the INFINI Radiofrequency System is substantially equivalent to the predicate system.

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

Lutronic, Inc.
c/o Jhung Won Vojir, Ph.D.
Global Regulatory Officer
Six Neshaminy Interplex, Suite 100
Trevose, PA 19053

June 25, 2013

Re: K121481
Trade/Device Name: INFINI Radiofrequency 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 11, 2013
Received: June 13, 2013

Dear Ms. Vojir:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

For Peter D. Rumm -S

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

Enclosure

Indications for Use

510(k) Number (if known): K121481

Device Name: INFINI Radiofrequency System

Indications for Use:

The INFINI Radiofrequency System is intended 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) (Part 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)

Joshua C. Nipper -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121481