K130283

510(k) Summary

MAR 7 2013

SPONSOR

Company Name:	F Care Systems NV
Company Address:	Kontichsesteenweg 54 2630 Aartselaar Belgium
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Contact Person:	Rudi Devers
Summary Prepared	September 18, 2012

Device Name

Trade Name:	EVRF
Common/Usual Name:	Electrosurgical Coagulation Device
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Product Code:	ONQ
Device Class:	Class II
Regulation Number:	21 CFR 878.4400

Predicate Device

Company	***Product***	***510(k) #***
Newlands Clinical Trials LTD	Veinwave TC3000	K083352

Device Description

The EVRF has 2 major parts: 1) the generator and 2) the needle. The generator creates the impulse. The impulse can be set at between in 0.1 second increments. The combination of these two settings means that highly accurate doses of energy can be delivered. The system utilizes a current of 4MHz .The power and impulse values are accurately maintained by a microprocessor and displayed on a LCD screen. The values can be digitally adjusted. The ultra-fine needle (Product Code KCW) has a diameter of 0.075 mm allowing for accurate operation and is protected by a specific isolating sheath. The vessel is thermocoagulated without damaging the epidermis and surrounding tissue. Needles are nickel. In case of a nickel allergy, gold needles are also available. The needles are disposable and can be used for a complete session. The combination of the generator and insulated needle allows for a very precise amount of energy to be delivered to exactly the right place.

Indications for Use

The EVRF System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.

Summary of Technological Characteristics

The EVRF method of action is the delivery of a controlled dose of high frequency energy to the vein, which stops the flow of blood to the area of concern. Once the flow of blood is interrupted, the appearance of the spider veins is greatly reduced or eliminated.
The power generator controls through a micro-controller the delivery of stable energy to the needle and creates the impulse. The system utilizes a current of 4MHz. The impulse can be set between 0.1 seconds and 0.8 second in 0.1-second increments. The power can be set between 1 watt and 25 watt in 1-watt increment for more precision in the treatment.

The remote control has been replaced by a touch screen display allowing an easy access to the function of the EVRF.

The number of impulse per second can be set to 1 or 2 impulses per second
The casing of the unit has been redesigned for marketing and ergonomic purposes only.
None of these improvements in design and technology are raising any new issues of safety or effectiveness

The needles used with this device are not cleared as a part of this device system, as they are a Class I, 510(k) exempt device (FDA Product Code KWC).
Needles are purchased from Ballet Technologies, Ltd,
Establishment Registration # 3005114964, as sterile, single-use, disposable needles and are device listed by Ballet as accessories to Needle-Type, High Frequency Epilators Classification Code KCW.

Conclusion: The information discussed above demonstrates that the EVRF device is substantially equivalent to the predicate device and does not raise new issues of safety and effectiveness.

12.2 Predicate Product Comparison Table

Feature	F Care Systems NV EVRF System	Newlands Clinical trials LTD Veinwave TC3000
510(k) Number		K083352
Classification and Product Code	878.4400 Product Code ONQ	878.4400 Product Code ONQ

Feature	F Care Systems NV EVRF System	Newlands Clinical trials LTD Veinwave TC3000
Indications for Use	The EVRF System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.	The Weinwave TC3000 System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.
OTC or Rx	Rx	Rx
Mode of Action	Thermocoagulation of tissue by administration of high frequency energy	Thermocoagulation of tissue by administration of high frequency energy
Mode of Delivery	Disposable Epilation Needle	Disposable Epilation Needle
Disposable Epilation Needle	Identical – Ballet Technologies LTD	Identical – Ballet Technologies LTD
Modality	Monopolar	Monopolar
Frequency (Monopolar)	4 MHz	4 MHz
Power Output – monopolar balanced at 500 ohms	25 watt	25 watt

12.3 Differences

Feature	F Care Systems NV EVRF System	Newlands Clinical trials LTD Veinwave TC3000
Frequency (Monopolar)	4 MHz	4 MHz

Software

The level of concern was determined to be moderate. The software information provided in this 510(k) followed the requirements found in FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* Issued May 11, 2005.

Safety Testing

The EVRF has passed the requirements for IEC 60601-1 and IEC 60601-1-2 EMC and 60601-2-2 electrical safety testing.

Comparison bench testing was performed –

- Comparison of output power setting and pulse setting was presented to establish substantial equivalence.

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

Underwriters Laboratories, Incorporated
% Mr. Ned Devine
Senior Staff Engineer
333 Pfingsten Road
Northbrook, Illinois 60062

March 7, 2013

Re: K130283
Trade/Device Name: EVRF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: ONQ
Dated: February 06, 2013
Received: February 27, 2013

Dear Mr. Devine:

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 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/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,

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 Form

Indications for Use

510(k) Number (if known): K130283

Device Name: EVRF System

Indications for Use:

The EVRF System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Surgical Devices Division Sign-Off 510(k) Number: K130283	Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=130036 Date: 2013.03.07 14:33:44 -05'00'