K083352

510(k) Summary

JUN 12 2009

Submitter Name: Submitter Address:	Newlands Clinical Trials, Ltd. Newlands Medical Centre 315 Chorley New Road Bolton, UNITED KINGDOM BL1 5BP
Establishment Registration #	3006786864
Owner/Operator #	10022858
Phone Number: Fax Number:	603 369 3550 603 369 3562
Contact Person:	William Greenrose
Date Prepared:	31 October 2008
Device Trade Name:	Veinwave/TC3000
Common Name	Electrosurgical Coagulation Device
Classification Name, Number & Product Code:	Electrosurgical cutting and coagulation device and accessories 878.4400 GEI
Predicate Devices:	Surgi-Max Electrosurgery Generator – K061174 - Ellman International Inc. Primaeva Medical System – K080145 - Primaeva Medical, Inc.
Device Description and Statement of Intended Use	Device Description: The Veinwave/TC3000 system consists of a power generator and a needle through which a controlled dose of radio frequency energy is delivered and is intended for epilation, and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.

	Intended Use: The Veinwave/TC3000 system is intended for epilation, and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.
Summary of Technological Characteristics	The Veinwave/TC3000 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 the delivery of energy to the needle and creates the impulse. The system utilizes a current of 4MHz. The impulse can be set between 0.2 seconds and 1 second in 0.1 second increments. The power can be set between 30% and 60% in 5% increments. 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 Veinwave/TC3000 device is substantially equivalent to the predicate devices.
Declarations	o This summary includes only information that is also covered in the body of the 510(k). o This summary does not contain any puffery or unsubstantiated labeling claims. o This summary does not contain any raw data, i.e., contains only summary data. o This summary does not contain any trade secret or confidential commercial information. o This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Veinwave/TC3000	Surgi-Max Electrosurgery Generator	Primaeva Medical System
510(k) Number	K083352	K061174	K080145
Manufacturer	Newlands Clinical Trials, Ltd.	Ellman International Inc.	Primaeva Medical, Inc.
Classification # & Product Code	878.4400 GEI	878.4400 GEI	878.4400 GEI
Intended Use	The Veinwave/TC3000 system is intended for epilation, and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.	Various, including: Hemostasis and Nonablative Coagulation for control of bleeding, epilation, and telangiectasia	The Primaeva Medical System is intended for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.
OTC or Rx	Rx	Rx	Rx
Mode of Action	Thermocoagulation of tissue by administration of high frequency energy	Thermocoagulation of tissue by administration of high frequency energy	Thermocoagulation of tissue by administration of high frequency energy
Mode of Delivery	Disposable epilation needle	Various, including disposable needles	Reusable Electrode Insertion Device and disposable Electrode Cartridge
Modality	Monopolar	Monopolar & bipolar	
Frequency (monopolar)	4 MHz	4 MHz	
Power Output – monopolar balanced at 500 ohms	~ 30 watt*	~ 60 watt*	

* Surgi-Max has a higher wattage output because it is intended for surgical applications on larger vessels in addition to small veins, while the Veinwave is only intended for the listed uses on small veins.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Newlands Clinical Trials Limited
% Qserve America, Incorporated
Mr. William Greenrose
President
220 River Road
Claremont, New Hampshire 03743

JUN 12 2009

Re: K083352
Trade/Device Name: Veinwave/TC3000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: ONQ
Dated: April 29, 2009
Received: May 1, 2009

Dear Mr. Greenrose:

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.

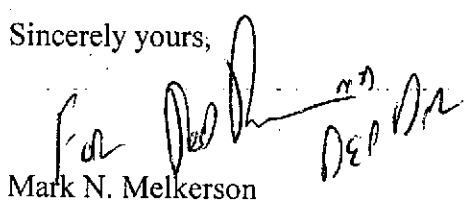
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Mark N. Melkerson
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): K083352

Device Name: Veinwave/TC3000

Indications For Use:

The Veinwave/TC3000 system is intended for epilation, and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R Ogden for mkm

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

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