K092191

Section 5 - 510(k) Summary

For

EXILIS

1. **Sponsor Information**

BTL Industries, Inc.
60 Walnut Avenue
Suite 190B
Clark, NJ 07066
Phone: (732) 381.6900
Fax: (732) 381.6911
Contact: Filip Donner, Product Manager

2. **Applicant Information**

Emergo Group
1705 S. Capital of Texas Highway
Suite 500
Austin, TX 78746
Phone: (512) 326.9997
Fax: (512) 326.9998
Contact: Richard Vincins, Senior Consultant QA/RA

3. **Date Prepared**

<date>

4. **Device Name**

Trade/Proprietary Name: EXILIS, EXILIS 5000
Common/Usual Name: Electrosurgical, Cutting & Coagulation Device
Classification Name: Electrosurgical, Cutting & Coagulation Device & Accessories
Classification Regulation: 878.4400
Product Code: GEI

5. **Predicate Devices**

- Iskra Medical – Iskra Medical Green IRF Prestige K083590; copy of 510(k) clearance letter in Appendix 5-A
- Thermage, Inc. – Thermage ThermaCool System K053365, K040135, K033942; copies of 510(k) clearance letters in Appendix 5-B through 5-D respectively
- Alma Lasers – Accent™ K072699, K070004; copies of 510(k) clearance letters in Appendix 5-E through Appendix 5-F respectively

6. Device Description

The EXILIS device is indicated for the primary treatment of dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids. EXILIS is a state-of-the-art device to apply therapy by a non-invasive method of high-frequency field.

The control unit of the device is fitted with a color touch screen, which significantly facilitates the use of the device. The device is equipped with a stylus (touch pen) for comfortable control of the touch screen. The vertically oriented design of the device enables to see the on-screen information from various positions of the operator. In addition, the brightness of the screen can be set to match the lighting in the surgery. The on-screen information will guide you through the entire therapy by means of easy setting of parameters using touch-screen buttons and knobs/keys on the device. For easier control, the applicator is equipped with buttons, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters.

Any therapeutic parameter can be set easily by simple use of the touch-screen buttons. During the entire therapy time the device informs you about the therapeutic method, the type of the therapy applied, the set power, and other necessary data.

The EXILIS device enables to insert the patient's name and additional corresponding information in its internal memory and link these data with the pre-defined or customer protocols. At the patient's next visit simply call his/her name on the device and apply the preset therapy. The EXILIS device is placed in a specially designed cart, the shape of which provides the maximum comfort of the handling and use of the device. Four stable castors ensure easy moving of the device in the office or surgery.

7. Intended Use

The EXILIS medical device is intended for use in non-invasive dermatologic and general surgical procedures.

8. Technological Characteristics and Substantial Equivalence

The EXILIS device shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices. The EXILIS device is similar in design and function to the predicate devices for the modes of operation and use.

The devices have a control unit that can be programmed utilized for the patient parameters. The devices are equipped with an input device either a stylus or touch screen to program the parameters. In addition, they are equipped with manual interface, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters. During operation the devices have an applicator instrument attached to the main unit. These devices all have the same intended use and indications for use as the EXILIS device.

9. Non-Clinical Testing

The device's hardware and software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The Device Hazard analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the hardware specifications and software specifications have met the acceptance criteria of each module and interaction of processes. The EXILIS device passed all testing and supports the claims of substantial equivalence and safe operation.

The EXILIS device complies with the applicable voluntary standards for Electromagnetic Compatibility and Safety. The device passed all the electrical and safety testing according to national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate devices. The safety and efficacy of the device is supported by the non-clinical testing. The verification and validation testing of the device software and electrical safety and EMC testing of the device was found acceptable and supports the claims of substantial equivalence.

11. Conclusion

The EXILIS device has the same intended use and technological characteristics as the predicate devices.

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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BTL Industries Ltd.
% Emergo Group
Mr. Richard Vincins
Senior Consultant QA/RA
1705 S. Capital of Texas Hwy., Suite 500
Austin, Texas 78746

Re: K092191
Trade Name: Exilis, Model 5000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulation Class: Class II
Product Code: GEI
Dated: November 5, 2009
Received: November 6, 2009

Dear Mr. Vincins:

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.

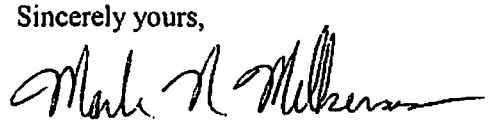
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

Section 4 - Indications for Use

510(k) Number (if known): K092191

Device Name: EXILIS

Indications for Use:

The EXILIS device is indicated for the primary treatment of dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids. EXILIS is a state-of-the-art device to apply therapy by a non-invasive method of high-frequency field.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

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

510(k) Number K092191