EndyMed™
THE 3DEEP™ COMPANY

K120513 P51 of 4

MAY - 8 2012

Section 2- 510(k) Summary

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510(K) SUMMARY

Glow by EndyMed

510(k) Number K_____

Applicant's Name: EndyMed Medical Ltd
7 Bareket Street,
North Industrial Park,
Caesarea, 30889 Israel
Tel: (972)4-630-9100
Fax: (972)4-630-9101

Contact Person: Yoram Levy, Qsite
31 Haavoda Street
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***Glow by EndyMed***

Preparation Date: January 30, 2012

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI, OUH
Regulation No: 21 CFR 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description: The ***EndyMed Glow*** is a non-invasive unit consists of a user interface, programmable logic controller (PLC), an RF power module, internal electronics, and treatment handpieces. The user interface allows the selection of treatment parameters by pressing on the treatment buttons; A LCD screen displays the current treatment settings. The PLC is a specially configured computer that provides the operational and safety functions of the system.

The system is connected to one or two out of 2 TC handpieces with different size electrode areas for different treatment sites, or to a FSR handpiece.

The RF power module provides RF energy to the handpiece, producing a sinusoidal signal at 1MHz frequency.

Intended Use Statement: The ***Glow by EndyMed*** is a noninvasive device intended for use in Dermatologic and General Surgical procedures.

The TC applicator is indicated for mild to moderate facial wrinkles and rhytides.

The FSR applicator is indicated for Dermatological procedures requiring ablation and resurfacing of the skin.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
EndyMed Imagine TC Skin Treatment System	**K083461**	Jul 24, 2009
EndyMed Fractional Skin Resurfacing (FSR) Applicator	**K101510**	Feb 17, 2011

Performance Standards:

Glow by EndyMed complies with:

- **EN 60601-1** (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
- **IEC 60601-1-2** (Electromagnetic compatibility (EMC)
- **ANSI AAMI 60601-2-2** for safety of high frequency surgical equipment.

A detailed description appears in **Section 14**.

Summary of the technological characteristics of the *Glow by EndyMed* compared to the predicate devices

The ***Glow by EndyMed*** has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices.
The TC applicator has exactly the same RF technology characteristics as the EndyMed Imagine TC Skin Treatment System

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(K0834610) and the FSR applicator has the same fractional RF technology as the EndyMed Fractional Skin Resurfacing (FSR) Applicator (K101510)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EndyMed Medical, LTd
% Yoram Levy
7 Bareket Street
North Industrial Park
Caesarea, 30889
Israel

MAY - 8 2012

Re: K120513
Trade/Device Name: Glow by EndyMed
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: OUH, GEI
Dated: February 15, 2012
Received: February 21, 2012

Dear Yoram Levy:

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,

for 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 STATEMENT

510(k) Number (if known): K120513

Device Name: ***Glow by EndyMed***

Indications for Use:

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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 General, Restorative and Neurological Devices~~
510(k) Number

Mark R Ogle for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120513