FEB 17 2011

510(K) SUMMARY

Fractional Skin Resurfacing (FSR) Applicator

510(k) Number K101510

Applicant's Name: EndyMed 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: ***Fractional Skin Resurfacing (FSR) Applicator***

Preparation Date: April 29, 2010

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

Device Description:

EndyMed's ***Fractional Skin Resurfacing (FSR) Applicator*** is a treatment handpiece to be attached to the FDA cleared EndyMed Imagine TC Skin Treatment System (**K08346**). The FSR Applicator tip emits bipolar RF energy that flows between electrodes to create micro-ablation points on the skin, forming superficial ablation with a volumetric non ablative heating effect in the dermis.

Intended Use Statement:

The ***Fractional Skin Resurfacing (FSR)*** Applicator is intended 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
Syneron Matrix RF Applicator	**K073572**	Sep 17, 2008
EndyMed Imagine TC Skin Treatment System	**K083461**	Jul 24, 2009

Performance Standards:

Fractional Skin Resurfacing (FSR) Applicator 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 Clinical performance data:

The safety and efficacy of the ***Fractional Skin Resurfacing (FSR) Applicator*** was evaluated in a performance testing.

The results of this testing clearly indicate that the Fractional Skin Resurfacing (FSR) Applicator offers a non-invasive, effective, safe device for skin resurfacing.

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Conclusion

The performance tests demonstrate that the **Fractional Skin Resurfacing (FSR) Applicator** is as safe, as effective, and performs at least as safely and effectively as the legally marketed device.

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.
% Qsite
Yoram Levy
31 Haavoda Street
Binyamina 30500
Israel

FEB 17 2011

Re: K101510
Trade/Device Name: Fractional Skin Resurfacing (FSR) Applicator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: OUH
Dated: January 21, 2011
Received: January 31, 2011

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

K101510

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: ***Fractional Skin Resurfacing (FSR) Applicator***

Indications for Use: The ***Fractional Skin Resurfacing (FSR)*** Applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin

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

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

510(k) Number K101510