510(K) SUMMARY

Intensif Applicator

510(k) Number K130501

Applicant's Name: EndyMed Medical Ltd.
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North Industrial Park,
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Contact Person: Yoram Levy, Qsite
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Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***Intensif Applicator*** **(Ilooda Secret)**
Common Name: **Electrosurgical RF applicator**

Preparation Date: February 7, 2013

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

Device Description:

EndyMed's ***Intensif Applicator*** is a treatment handpiece to be attached to the FDA cleared EndyMed Imagine TC Skin Treatment System (K08346) (EndyMed Pro). The ***Intensif Applicator*** has a custom grid array of micro electrodes that is used to deliver the energy into the tissue.
The ***Intensif Applicator*** tip emits bipolar RF energy that flows between electrodes to create thermal heating of the tissue for hemostasis and coagulation

The ***Intensif Applicator*** consists of:

- Disposable treatment element (tip)
- RF electrodes on a disposable tip

- Operation trigger

Intended Use Statement:

The ***Intensif Applicator*** is intended for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

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

Device Name	510(k) No	Date of Clearance
Primaeva Medical System	K080145	Feb 28, 2008
EndyMed FSR	K101510	Feb 17, 2011
EndyMed Imagine TC Skin Treatment System	K083461	Jul 24, 2009

Performance Standards:

Intensif Applicator complies with the following standards:

- IEC 60601-1:2005 / EN 60601-1:2006 Medical electrical equipment – part 1 General requirements for basic safety and essential performance, 3rd edition
- IEC/EN 60601-1-2 Electromagnetic compatibility (EMC)

Summary of Technologies

The ***Intensif Applicator*** uses microneedles and implies 1MHz RF energy to achieve their intended use.

Performance Bench Testing Data

The safety and efficacy of the ***Intensif Applicator*** were established by a series of performance tests. Lab performance tests, design validation and software verification and validation. Verification and testing have shown that the ***Intensif Applicator*** device performs according to its specifications.

The following tests were conducted:

- ***Intensif Applicator*** 's power control and accuracy
- ***Intensif Applicator***'s safety features functionality
- ***Intensif Applicator*** needle depth validation.

Summary of Preclinical Data

In order to evaluate efficacy and safety of the ***Intensif Applicator***, a few Ex Vivo laboratory studies and Ex Vivo animal studies tests were conducted, while the ***Intensif Applicator*** was connected to the ***EndyMed PRO*** (K083461) treatment console.

The results of these studies clearly indicate that the treatment with ***Intensif Applicator*** connected to the ***EndyMed PRO*** system produces thermal and biological effects similar to previously FDA cleared fractional skin hemostasis and coagulation devices

Summary of Clinical performance data:

The safety and efficacy of the ***Intensif Applicator*** was evaluated in a performance and preclinical testing.

The results of this testing clearly indicate that the ***Intensif Applicator*** offers a minimally invasive, effective, safe device for skin hemostasis and coagulation.
No clinical studies were conducted.

Substantial Equivalence

Intensif Applicator device has the same intended use and similar indications as its predicate devices. The technology of the predicate devices is also the same.
The envelope of power and frequency of the submitted ***Intensif Applicator*** is covered by the envelopes of its predicate devices. Any minor differences in the human interface and accessories design do not raise any new types of safety and effectiveness issues, as verified by performance and ex vivo testing. Therefore the **Intensif Applicator** nonclinical and ex vivo testing submitted demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device and thus is substantially equivalent to its predicate devices.

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

March 13, 2014

EndyMed Ltd.
% Mr. Yoram Levy
Qsite
31 Haavoda Street
Binyamina, Israel 30500

Re: K130501
Trade/Device Name: Intensif Applicator
Regulation Number: 21 CFR 878.4800
Regulation Name: Electrosurgical, Cutting, Coagulation, & Accessories
Regulatory Class: Class II
Product Code: OUH, GEI
Dated: January 21, 2014
Received: January 27, 2014

Dear Mr. 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 contact 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. 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,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EndyMed™
THE 3DEEP™ COMPANY

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130501

Device Name: ***Intensif Applicator***

Indications for Use: The ***Intensif Applicator*** is intended for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

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)

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=1300369
Date: 2014.03.11 12:24:08 -04'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K130501