510(K) SUMMARY

EndyMed Newa™

510(k) Number K130793

Applicant's Name: EndyMed Medical Ltd.
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AUG 16 2013

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Trade Name: *Newa™*

510(k) Summary Preparation Date: March 19, 2013

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

Intended Use Statement:

The EndyMed Newa is a prescription home use device intended for non-invasive treatment of mild to moderate facial wrinkles and rhytides

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

Device Name	Manufacturer	510k No	Date of Clearance
Imagine TC Skin Treatment System	EndyMed Medical Ltd. (previously EndyMion Medical)	K083461	Jul 24, 2009
Palomar LOI System	Palomar Medical Technologies, Inc.	K090525	June 1, 2009

Device Description:

The *Newa™* is a noninvasive, non-ablative, prescription home use hand held device consisting of:

- User interface
- Programmable Logic controller (PLC)
- RF power module
- Power Supply
- RF Electrodes

The interface allows the selection of heating level by using the Power Level Switch as follows:

- "0" mode = the device is "OFF".
- "1" mode = low heating level.
- "2" mode = high heating level.

The PLC is a specially configured computer that provides the operational and safety function of the system.

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

Based on **3DEEP®** technology, the *Newa™* is comprised of 3 pairs of bipolar RF electrodes. The RF is emitted into the skin creating enough thermal effect to induce collagen remodeling with no ablative thermal damage in the epidermis, dermis or hypodermis.

Performance Standards

Newa ™ complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the following voluntary standards:

- IEC 60601-1:2005 Medical electrical Equipment -- Part 1: General requirements for safety.
- IEC 60601-1-2:2004 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-1-11:2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Summary of Clinical performance data

Subjects were asked to perform task scenarios, simulating the use of the *Newa™* device, for independent treatment under the investigator's observation. Following task

performance, subjects were provided with the ***Newa™***

This study enrolled 69 subjects, 62 of these completed the required follow-up at 3 months after the last treatment. Of the subjects who completed the 3 month follow-up 85% were determined to be successful based on 2 of the 3 blinded evaluators agreeing that they observed a decrease of at least 1 in the Fitzpatrick Wrinkle Severity Score at 3 months post the last treatment

Comparison with Predicate Devices:
The ***Newa™*** and its predicate devices are class II devices; ***Newa™*** and *Imagine TC Skin Treatment System* have the same clinical indication, are based on the same technology of RF delivery and are classified under the same product code and regulation number. ***Newa™*** and Palomar LOI System have similar intended uses.

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

EndyMed Medical Ltd.
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August 16, 2013

Re: K130793
Trade/Device Name: *Newa*^{TM}
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical, cutting & coagulation device & accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 16, 2013
Received: July 19, 2013

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,

Mark N. Melkerson -S

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130793

Device Name: *Newa™*

Indications for Use: The EndyMed *Newa™* is a prescription home use device intended for non-invasive treatment of mild to moderate facial wrinkles and rhytides

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)

Joshua C. Nipper -S

(Division Sign-off)
Division of Surgical Devices
510(k) Number K130793