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

February 7, 2017

EndyMed Medical Ltd.
% Yoram Levy
Qsite General Manager
Qsite
31 Haavoda St.
Binyamina, 30500 Israel

Re: K161715
Trade/Device Name: EndyGel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: December 29, 2016
Received: January 4, 2017

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 contact the Division of Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161715

Device Name
EndyGel

Indications for Use *(Describe)*
EndyGel is an Electroconductive gel media used with external electrode to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ENDYMED™
3DEEP SKIN SCIENCE

510(K) SUMMARY

EndyMed's EndyGel™
510(k) Number K161715

Applicant's Name: EndyMed Medical Ltd.
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Fax: (972)4-630-9101

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

Trade Name: ***EndyGel™***

510(k) Summary Preparation Date: February 2, 2017

Classification: **Name**: Electroconductive media
Product Code: GYB
Regulation No: 21 CFR 882.1275
Class: II
Panel: Neurology

Indications for Use (IFU) Statement:

EndyGel™ is an Electroconductive gel media used with external electrode to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.

Device Description:

EndyMed's ***EndyGel™*** is an Electroconductive gel media used with external electrode to enhance electrical conductivity by reducing the impedance (resistance to alternating current) of the radiofrequency signals path from the electrode surface between the electrode surface and the skin.

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

Predicate/ Reference	**Device Name**	**Manufacturer**	**510k No.**	**Clearance Date**
Predicate	Electro-Gel	Electro-Cap International Inc.	K111717	Jan 05 2012

Comparison table with the predicate

	EndyMed EndyGel (proposed)	**Predicate device: Electro-Gel (K111717)**
Device Class	Class II	same
Classification Panel	Neurology	same
Product Code	GYB	Same
Regulation Description	Electroconductive media	Same
Regulation number	21 CFR 882.1275	Same

	EndyMed EndyGel (proposed)	**Predicate device: Electro-Gel (K111717)**
Indications for Use (IFU) statement	EndyMed's ***EndyGel™*** is an Electroconductive gel media used with external electrode to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.	The **Electro-Gel** device is intended for use with external electrodes as the conductor between the scalp and the electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.
Principles of Operation	EndyMed's ***EndyGel™*** functions as a conductor between the skin and the electrodes. EndyMed's ***EndyGel™*** is intended to used prior to Handpiece's electrodes placement to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin. The energy is then transferred via the gel to the patient's tissue.	Same
Body contact	Intact Skin	Same

	EndyMed EndyGel (proposed)	Predicate device: Electro-Gel (K111717)
Biocompatibility	Complies with requirements of ISO 10993-1, including: Cytotoxicity (ISO 10993-5), Irritation and Sensitization (ISO 10993-10)	Same
Sterilization	Provided non-sterile	Same
Shelf life	2 years	3 years
Impedance (at 1 MHz)	527.68	549.71
Conductive material	Water (Aqua) with immersed Triethanolamine	Water (Aqua) with immersed Sodium chloride
Composition	• Water (solvent) • Carbomer (gel forming) • Triethanolamine (Buffering) • Methylisothiazolinone and Methylcloroisothiazolinone (preservative)	• Water (solvent) • Sodium Chloride (preservative) • Aragum T-1998 (thickner) • Potassium Bitartrate • (Stabilizer) • Glycerin (lubricant) • Methylparaben (preservative) • Propylparaben (preservative)
pH	7.15-7.33	6.99

Substantial Equivalent Discussion

The EndyGel, like its predicate device, is indicated for use as an Electroconductive gel media used with external electrode to reduce the impedance (resistance to alternating current) of the contract between the electrode surface and the skin.

The EndyGel and the predicate device have similar technological Electroconductive gel media.

The impedance of the EndyGel is within 4% and the pH within 2.2% compared to the predicate device. The difference in total impedance and in pH between the two gels is negligible and do not impact the safety and effectiveness of the EndyGel.

Performance

The safety and efficacy of the ***EndyGel™*** were established by a series of performance tests, including biocompatibility testing, electrical performance and stability.

The design of ***EndyGel™*** was done in accordance with EndyMed Medical Ltd. quality management system and design controls per 21CFR820 and ISO 13485. V&V and compliance testing, including: Biocompatibility testing, Electrical Performance testing and Stability testing, were successfully conducted and did not raise any new safety questions or identify any new risks.

Standards:

The ***EndyGel™*** complies with the following standards

1. ISO 14971-1:2009 Risk management for medical devices
2. ISO13485:2003 Medical devices -- Quality management systems -- Requirements for 0regulatory purposes.
3. ISO 10993-1:2009 Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process.
4. ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

5. ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
6. EN ISO 15223-1 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

Conclusion:

The ***EndyGel™***, like its predicate devices, is indicated for use as an Electroconductive gel media used with external electrode to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.

The ***EndyGel™***, the predicate device and reference device have similar technological features of an Electroconductive gel media.

Results of tests, performed with the proposed ***EndyGel™*** demonstrate that it is as safe and effective as its predicate device, without raising any new safety and/or effectiveness concerns.

Therefore the ***EndyGel™*** is substantially equivalent to its predicate device.

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