November 25, 2020

Guangzhou Xinbo Electronic Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, 510700 China

Re: K200402
Trade/Device Name: DR-HO'S Electro Therapy Conductive Gel
Regulation Number: 21 CFR 882.175
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: August 13, 2020
Received: August 28, 2020

Dear Cassie Lee:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K200402

Device Name
DR-HO'S Electro Therapy Conductive Gel (Model: DHGEL)

Indications for Use *(Describe)*
DR-HO'S Electro Therapy Conductive Gel is intended for use with TENS (transcutaneous electrical nerve stimulation) and EMS (electric muscle stimulation) therapy. The Conductive Gel is used with external electrodes to reduce the impedance 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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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

510(k) Owner's Name: Guangzhou Xinbo Electronic Co., Ltd.
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Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
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Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Date of the summary prepared: November 25, 2020

3. Subject Device Information

Company Name: Guangzhou Xinbo Electronic Co., Ltd.
Trade/Device Name: DR-HO'S Electro Therapy Conductive Gel
Model Name: DHGEL
Classification Name: Media, Electroconductive
Common Name: Electroconductive Media
Product Code: GYB
Regulation Number: 882.1275
Regulatory Class: 2

4. Predicate Device Information

Sponsor	THE DEZAC GROUP	EndyMed Medical Ltd.	Spes Medica S.r.l.
Device Name	Conductive Gel	EndyGel™	Tech Dots
510(k) Number	K022006	K161715	K190050
Product Code	GYB	GYB	GYB
Regulation Number	882.1275	882.1275	882.1275
Regulation Class	II	II	II

5. Device Description

DR-HO'S Electro Therapy Conductive Gel can be used with any of dozens of stimulating devices that are legally sold, to reduce the impedance between the skin and the stimulating device. It consists of Purified water: 98.25%, Carbopol: 0.5%, Glycerin: 1%, Sodium hydroxide: 0.2% and Triclosan: 0.05%. And the Purified water used as the solvent, the Carbopol as a gel forming material, the Glycerin as a Moisturizing, the Sodium hydroxide as a Buffering and the Triclosan as a preservative.
The DR-HO'S Electro Therapy Conductive Gel is used on intact skin surfaces. The entire surface of DR-HO'S Electro Therapy Conductive Gel is very conductive, sprayed evenly on the stimulation device, so that the current is evenly distributed. The gel is to be generously applied to the area where an electrode will be used. The gel can be washed off the skin after use.

6. Intended Use / Indications for Use

DR-HO'S Electro Therapy Conductive Gel is intended for use with TENS (transcutaneous electrical nerve stimulation) and EMS (electric muscle stimulation) therapy. The Conductive Gel is used with external to reduce the impedance of the contact between the electrode surface and the skin.

7. Test Summary

DR-HO'S Electro Therapy Conductive Gel (Model: DHGEL) has been evaluated the safety and performance by lab bench testing as following:

Test Item	Purpose of the test	Reference Standard	Acceptance criteria	Test results
In vitro Cytotoxicity Test	Under the research conditions, determine whether the target device extract is cytotoxic.	ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Pass
Skin Sensitization Test	Under the research conditions, determine whether the non-polar and polar extracts of the target device are sensitive.	ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Pass

Skin Irritation Test	Under the research conditions, determine whether the non-polar and polar extracts of the target device are irritating.	ISO 10993-10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Pass
Usability Study	To study how usability will be performed in subject device in order to comply with IEC 62366-1 and IEC 60601-1-6	IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1 Edition 1.0 2015-02, Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	The subject device can meet the usability goal of IEC 60601-1-6 and IEC 62366-1 standards.	Pass
Shelf Life Test	To study whether the performance of subject device can meet the 2-year shelf life requirements	ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices; Guidance document for the "Shelf Life of Medical Devices" issued in April 1991	All items (Visual Inspection, pH, conductivity, Impedance and Microbiological indicators) tested on both before and after aging samples meet performance required.	Pass

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Electrode is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate)	Predicate Device 2	Predicate Device 3	Predicate Device 4	Remark
Device Name and Model	DR-HO'S Electro Therapy Conductive Gel Model: DHGEL	Conductive Gel	EndyGel™	Tech Dots - Conductive gel	Electro-Gel	--
510(k) Number	Applying	K022006	K161715	K190050	K111717	--
Product Code	GYB	GYB	GYB	GYB	GYB	SE
Intended Use / Indications for Use	DR-HO'S Electro Therapy Conductive Gel is intended for use with TENS (transcutaneous electrical nerve stimulation) and EMS (electronic muscle stimulation) therapy. It is to be use to moisten the electrodes and the skin, to reduce impedance of the contact between the electrode surface and the skin. This helps to provide a more comfortable and effective treatment.	The Conductive Gel is intended for use with TENS (transcutaneous electrical nerve stimulators) and EMS(electrical muscle stimulators). The Conductive Gel is used with external to reduce the impedance of the contact between the electrode surface and the skin.	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.	Tech Dots are intended for use in clinical and research EEG/EP recordings from humans. They are used with external electrodes as the conductor between the scalp and recessed electrodes to reduce impedance between the electrode surface and the skin.	This device is intended for use in clinical and research EEG/EP recordings from humans. The Electro-Gel is used with external electrodes as the conductor between the scalp and the (recessed) electrodes. It also reduces impedance (resistance to alternating current) between the electrode surface and the skin.	SE Note 1
Regulation Number	882.1275	882.1275	882.1275	882.1275	882.1275	SE

Body contact	Intact Skin	Not publicly available	Intact Skin	Intact Skin	Intact Skin	SE
sterilization	non-sterile	Not publicly available	non-sterile	non-sterile	non-sterile	SE
Shelf life	2 years	Not publicly available	2 years	3 years	1 year	SE
Weight	250g / bottle	Not publicly available	Not publicly available	0.14 ± 0.01 g per Dot	16 ounce, 32 ounce, 128 ounce	--
Impedance	500Ω	Not publicly available	527.68Ω	80 ± 10 Ohm	≤500Ω	SE Note 2
Conductive material	Purified water with Sodium hydroxide	Not publicly available	Water (Aqua) with immersed Triethanolamine	Salt (NaCl)	Salt (NaCl)	SE Note 3
Composition	- Purified water (solvent); - Carbopol (gel forming); - Glycerin (Moisturizing); - Sodium hydroxide (Buffering); - Triclosan (preservative)	Not publicly available	- Water (solvent); - Carbomer (gel forming); - Triethanolamine (Buffering); - Methylisothiazolinone(preservative)	- Water - Glycerol (vegetable origin) - Polyacrylate co-polymer (proprietary) - Potassium chloride	- Aragum - Glycerine - Methyparaben - Propylprarben	SE Note 4
Percent concentration of each ingredient	- Purified water: 98.25% - Carbopol: 0.5% - Glycerin: 1% - Sodium hydroxide: 0.2% - Triclosan: 0.05%	Not publicly available	Not publicly available	Not publicly available	Not publicly available	--
Conductivity (S/m)	2 mS/cm	Not publicly available	Not publicly available	2 mS/cm	Not publicly available	SE

pH	7.0 - 7.5	Not publicly available	7.15 - 7.33	4 - 5	4.5 - 6.0	SE Note 5
Biocompatibility	Complied with ISO 10993-5, ISO 10993-10	Not publicly available	Complied with ISO 10993-5, ISO 10993-10	Complied with ISO 10993-5, ISO 10993-10	Complied with ISO 10993-5, ISO 10993-10	SE
Cytotoxicity	Yes	Not publicly available	Yes	Yes	Yes	SE
Irritation	Yes	Not publicly available	Yes	Yes	Yes	SE
Sensitization	Yes	Not publicly available	Yes	Yes	Yes	SE
Operating Environment	Temperature: 5~40°C Humidity: ≤80%RH Atmospheric Pressure: 86~106kPa	Not publicly available	Not publicly available	Not publicly available	Not publicly available	--
Storage Environment	Temperature: 5~40°C Humidity: ≤95% RH Atmospheric Pressure: 50~106 kPa	Not publicly available	Not publicly available	Not publicly available	Not publicly available	--

Comparison in Detail(s):

Note 1:

Although the “Intended use” of subject device is a little different from predicate devices, we can find that their core is to reduce the impedance to the skin without affecting the use of the device. So the slight differences in description will not raise any safety or effectiveness issue.

Note 2:

Although the “Impedance” of the subject device is a little different from the predicate devices, and it has an impedance of 500Ω which is very similar to the impedance 527.68Ω of the predicate device (K161715) and ≤500Ω of the predicate device (K111717). Considering that, no new questions of safety or effectiveness are raised.

Note 3:
Although the “Conductive material” of the subject device is different from predicate devices, but they all composed of water (solvent) and / or conductive buffer to achieve conductivity of the device. So the slight differences in description will not raise any safety or effectiveness issue.

Note 4:
Although the specific materials of subject device are not the same as predicate devices, but both the materials for the subject device and for the predicate device have substantially equivalent function (for solvent, gel forming, Moisturizing, Buffering, preservative) in the process of producing the gel, so these differences do not raise different issue of safety or effectiveness.

Note 5:
Although the “pH” of the subject device is a little different from predicate device (K161715), but the difference is slight, and it is close to the pH value of human skin surface, the pH is closed to 7 (neutral), beside, even the water for drinking is required <8 (neutral to Alkaline), which can prove the pH of subject device is safe. So the slight differences in description will not raise any safety or effectiveness issue.

Finial Conclusion:
The subject device “DR-HO'S Electro Therapy Conductive Gel, (Model: DHGEL)” is Substantial Equivalent to the predicate devices K022006, K161715, K190050 and K11171.