December 13, 2022

Top-Rank Health Care Co.,Ltd.
℅ Cassie Lee
Manager
Guangzhou GLOMED Biological Technoloy Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K222770
Trade/Device Name: Conductive Gel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive media
Regulatory Class: Class II
Product Code: GYB
Dated: September 14, 2022
Received: September 14, 2022

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,

Tushar Bansal -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222770

Device Name
Conductive Gel

Indications for Use *(Describe)*
Intended for use with electric stimulation therapy devices, such as TENS and EMS. Conductive Gel is used with external electrodes to reduce the impedance of the contact between the electrode 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. Date of the summary prepared: December 8, 2022

2. Submitter's Information

Sponsor Name: Top-Rank Health Care Co. Ltd.

Address: Mashan Village, Dongguan Street, Shangyu District, Shaoxing City, Zhejiang Province, China. 312300

Establishment Registration Number: Applying

Contact name: Gangfeng Lou

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Application Correspondent:

Contact Person: Ms. Cassie Lee

Company: Guangzhou GLOMED Biological Technology Co., Ltd.

Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China

Tel: +86 20 8266 2446

Email: regulatory@glomed-info.com

3. Subject Device Information

Type of 510(k): Traditional

Company Name: Top-Rank Health Care Co. Ltd.

Trade/Device Name: Conductive Gel

Model Name: TG01-50, TG01-65, TG01-90, TG01-100, TG01-125, TG01-160, TG01-200, TG01-250

510k Review Panel: Neurology

Classification Name: Media, Electroconductive

Product Code: GYB

Regulation Number: 21 CFR 882.1275

Regulatory Class: II

Intended Use / Indications for Use:

Intended for use with electric stimulation therapy devices, such as TENS and EMS. Conductive Gel is used with external electrode to reduce the impedance of the contact between the electrode and the skin.

4. Predicate Device Information

Predicate Device:

Sponsor: Guangzhou Xinbo Electronic Co., Ltd.

Common Name: Media, Electroconductive

Trade/Device Name: DR-HO'S Electro Therapy Conductive Gel

Classification Name: Media, Electroconductive

510(K) Number: K200402

510k Review Panel: Neurology

Product Code: GYB

Regulation Number: 21 CFR 882.1275

Regulatory Class: II

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.

5. Device Description

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 Conductive Gel is used on intact skin surfaces. The entire surface of Conductive Gel is very conductive, smeared 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. Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Predicate Device	Remark
Device Name and Model	Conductive Gel Model: TG01-50, TG01-65, TG01-90, TG01-100, TG01-125, TG01-160, TG01-200, TG01-250	DR-HO'S Electro Therapy Conductive Gel Model: DHGEL	--
510(k) Number	K222770	K200402	--
Product Code	GYB	GYB	SE
Intended Use / Indications for Use	Intended for use with electric stimulation therapy devices, such as TENS and EMS. Conductive Gel is used with external electrode to reduce the impedance of the contact	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	Similar Note 1

	between the electrode and the skin.	is used with external to reduce the impedance of the contact between the electrode surface and the skin.	
Regulation Number	882.1275	882.1275	SE
Body contact	Intact Skin	Intact Skin	SE
Sterilization	Non-Sterile	Non-Sterile	SE
Shelf life	2 years	2 years	SE
Impedance (at 1 MHz)	≤500Ω	500Ω	Similar Note 2
Material	Purified water (solvent); Carbopol (gel forming); Glycerin (Moisturizing); Sodium hydroxide (Buffering); Triclosan (preservative)	Purified water (solvent); Carbopol (gel forming); Glycerin (Moisturizing); Sodium hydroxide (Buffering); Triclosan (preservative)	SE
Percent concentration of each ingredient	- Purified water: 98.25%; - Carbopol: 0.5%; - Glycerin: 1%; - Sodium hydroxide: 0.2%; - Triclosan: 0.05%	- Purified water: 98.25% - Carbopol: 0.5% - Glycerin: 1% - Sodium hydroxide: 0.2% - Triclosan: 0.05%	SE
pH	6.5 ~ 7.5	7.0-7.5	Similar Note 3
Preservative	Triclosan	Triclosan	SE

Biocompatibility	Complied with ISO 10993-5, ISO 10993-10	Complied with ISO 10993-5, ISO 10993-10	SE
Cytotoxicity	Yes	Yes	SE
Irritation	Yes	Yes	SE
Sensitization	Yes	Yes	SE
Operating Environment	Temperature: 5~40°C Humidity: ≤80%RH Atmospheric Pressure: 86~106kPa	Temperature: 5~40°C Humidity: ≤80%RH Atmospheric Pressure: 86~106kPa	SE
Storage Environment	Temperature: 5~40°C Humidity: ≤95% RH Atmospheric Pressure: 50~106 kPa	Temperature: 5~40°C Humidity: ≤95% RH Atmospheric Pressure: 50~106 kPa	SE

Comparison in Detail(s):

Note 1:

Although the “Intended Use / Indications for Use” of subject device is slightly different from predicate device, it's just a difference in how they are described. So, the slight difference will not raise any safety or effectiveness issue.

Note 2:

Although the “Impedance” of the subject device is lower than the predicate device, it does not affect the effectiveness of the product in use. So, the slight difference in Impedance will not raise any safety or effectiveness issues.

Note 3:

Although the “pH” of the subject device is a little different from the predicate device, both of them are close to the pH value of the human skin surface, the pH is closed to 7 (neutral). So, the slight difference in pH will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Summary of Non-Clinical Testing

Conductive Gel (Model: TG01-50, TG01-65, TG01-90, TG01-100, TG01-125, TG01-160, TG01-200, TG01-250) 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 this study, the Test Sample were non-cytotoxicity to L929 cells.	Pass
Skin Sensitization Test	Under the research conditions, to evaluate the possibility of skin sensitization after topical applications of the test sample on the skin of guinea pig.	ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Under the conditions of this study, the frequency of positive challenge results in sample extract and Negative control animals are 0%, the Positive control is 100%.	Pass

Skin Irritation Test	Under the research conditions, to evaluate the possibility of skin irritation after single topical applications of the test sample on the skin of rabbits.	ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Under the conditions of this study, the test sample induce negligible irritation in a rabbit skin single exposure test.	Pass
Usability Study	To study how usability will be performed in subject device in order to comply with IEC 62366-1	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 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 (Exterior, Package, pH, Impedance and conductivity) tested on both before and after aging samples meet the performance required.	Pass

7.2 Summary of Non-Clinical Testing

No clinical study is included in this submission.

8. Final Conclusion

The subject device “Conductive Gel, (Model: TG01-50, TG01-65, TG01-90, TG01-100, TG01-125, TG01-160, TG01-200, TG01-250)” is as safe and effective and substantially equivalent to the legally marketed predicated K200402.