November 8, 2021

Wuhan Greentek Pty Ltd.
Yarong Liu
Manager
Room 03-2, Floor 3, Dingye Building, Phase III,
International Enterprise Center, Special No. 1, Guanggu Ave
Wuhan, 430074
China

Re: K212787
Trade/Device Name: GT5 conductive & abrasive gel
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive media
Regulatory Class: Class II
Product Code: GYB
Dated: August 13, 2021
Received: September 1, 2021

Dear Yarong Liu:

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,

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)*
K212787

Device Name
GT5 conductive & abrasive gel

Indications for Use *(Describe)*
GT5 conductive & abrasive gel is intended for use in clinical and research EEG/EP recordings from humans. It can be not only used as skin-prep gel to abrade the skin surface lightly in order to reduce impedance (resistance to alternating current) efficiently, but also used as the conductor between the scalp and the external electrodes to reduce impedance between the electrode surface and the skin. GT5 conductive & abrasive gel is not intended for use with stimulating electrodes.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 13 August 2021

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Wuhan Greentek Pty Ltd.
Address:	Room 03-2, Floor 3, Dingye Building, Phase III, International Enterprise Center, Special No.1, Guanggu Avenue, East Lake High-tech Development Zone, Wuhan, CHINA 430074
Contact person:	Yarong Liu
Title:	Manager
E-mail:	lyr@gtsensor.com
Tel:	+86-27-88185488

2. Device Identification

Trade/Device Name:	GT5 conductive & abrasive gel
Common Name:	Electroconductive Media
Regulations:	21 CFR 882.1275
Classification Name:	Media, Electroconductive
Regulation Class:	Class II
Product Code:	GYB

3. Predicate Device

510(K) number:	K111717
Device Name:	Eletro-Gel
Manufacturer:	Electro-Cap International, Inc.
Regulations:	21 CFR 882.1275
Classification Name:	Media, Electroconductive
Regulation Class:	Class II
Product Code:	GYB

510(K) number:	K190050
Device Name:	Tech Dots – Adhesive and Conductive Gel
Manufacturer:	Spes Medica S.r.l.
Regulations:	21 CFR 882.1275
Classification Name:	Media, Electroconductive
Regulation Class:	Class II
Product Code:	GYB

510(K) number:	K970694
Device Name:	Model 1700, HydroPrep

Manufacturer:	Physiometrix, Inc.
Regulations:	21 CFR 882.1275
Classification Name:	Media, Electroconductive
Regulation Class:	Class II
Product Code:	GYB

510(K) number:	K885306
Device Name:	NuPrep
Manufacturer:	WEAVER & COMPANY
Regulations:	21 CFR 870.2360
Classification Name:	Media, Electroconductive
Regulation Class:	Class II
Product Code:	DRX

4. Device Description

GT5 conductive & abrasive gel is intended for use in clinical and research EEG/EP recordings from humans. It can be not only used as skin-prep gel to abrade the skin surface lightly in order to reduce impedance (resistance to alternating current) efficiently, but also used as the conductor between the scalp and the external electrodes to reduce impedance between the electrode surface and the skin. The electrical activity of the brain is transferred to the electrode and then to EEG instruments and computer equipment.
GT5 conductive & abrasive gel is for use with external electrodes only.
GT5 conductive & abrasive gel is an off-white color, opaque, no adverse smell gel with sodium chloride as the conductive material combined with thickening agents, emulsifiers, humectants, preservatives and abrasive particles. With the abrasive particles in the gel, the gel can be also used as skin preparation by being applied to the skin surface to rub the skin lightly in order to reduce skin impedance efficiently and increase signal quality recorded with EEG electrodes.
The composition of GT5 conductive & abrasive gel is as follows:
Glycerin, Sodium chloride, Water, Methylparaben, Propylparaben, Sodium Carboxymethyl cellulose, Alkyl indican, Aluminum Oxide.
The pH range is 6.5-7.5, and the impedance at 10Hz is 0.2K Ohm or less. The conductivity is 18±0.5 mS/cm. GT5 conductive & abrasive gel is available in the following sizes: a pre-filled syringe of 20g, a tube of 100g, a bottle container of 473g, a bottle container of 946g. Shelf life is 3 years if stored properly, i.e. kept with containers tightly closed and at room temperature.

5. Indication for use

GT5 conductive & abrasive gel is intended for use in clinical and research EEG/EP recordings from humans. It can be not only used as skin-prep gel to abrade the skin surface lightly in order to reduce impedance (resistance to alternating current) efficiently, but also used as the conductor between the scalp and the external electrodes to reduce impedance between the electrode surface and the skin. GT5 conductive & abrasive gel is not intended for use with stimulating electrodes.

6. Comparison to Predicate Device

Table 1 Compares features and specifications of the GT5 conductive & abrasive gel under review to the predicates *Electro-Gel* and *Tech Dots - Adhesive and Conductive Gel*.

Feature	GT5 conductive & abrasive gel (this submission)	Electro-Gel	Tech Dots – Adhesive and Conductive Gel	Comparison
510(k) number	-	K111717	K190050	-
Product Code	GYB	GYB	GYB	Same
Indications for use	GT5 conductive & abrasive gel is intended for use in clinical and research EEG/EP recordings from humans. It can be not only used as skin-prep gel to abrade the skin surface lightly in order to reduce impedance (resistance to alternating current) efficiently, but also used as the conductor between the scalp and the external electrodes to reduce impedance between the electrode surface and the skin. GT5 conductive & abrasive gel is not intended for use with stimulating electrodes.	Electro-Gel 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.	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	The core of the "indications for use" of the subject device is the same to predicate devices, which is to reduce the impedance to the skin without affecting the use of EEG equipments. The slight differences in description will not raise any safety or effectiveness issue.
Regulation Name	Media, Electroconductive	Media, Electroconductive	Media, Electroconductive	Same
Regulation	882.1275	882.1275	882.1275	Same

Number				
Environment of use	Electrophysiological	Electrophysiological	Electrophysiological	Same
Intended user	Neurologists	Neurologists	Neurologists	Same
Target patient	Adult and children	Adult and children	Adult and children	Same
Where used	Topically on intact skin	Topically on intact skin	Topically on intact skin	Same
Conductive material	Salt (NaCl)	Salt (NaCl)	Salts (KCl)	Same
Thickening agent	Sodium Carboxymethyl cellulose, Glycerin	Aragun, Glycerin	Polyacrylate copolymer, Glycerol	Equivalent to predicates
Composition	Glycerin, Sodium chloride, Water, Methylparaben, Propylparaben, Sodium Carboxymethyl cellulose, Alkyl indican, Aluminum Oxide	Glycerin, Sodium Chloride, Water, Methylparaben, Propylparaben, Aragun T-1998, Potassium Bitartrate	Water, Glycerol, Polyacrylate copolymer, Potassium chloride	Although the specific materials of subject device are not exactly the same as predicate devices, but both the materials for the subject device and for the predicate devices have substantially equivalent function (for solvent, gel forming, moisturizing, preservative) in the process of producing the gel, so these differences do not raise different issue of safety or effectiveness.
Sterilization	Provide non sterile	Provide non sterile	Provide non sterile	Same

method				
Shelf-life	3 years	1 year	3 years	Same
Chemical Safety	No OSHA PEL	No OSHA PEL	No OSHA PEL	Same
Preservative	Methylparaben, Propylparaben	Methylparaben, Propylparaben	No preservative	Same
Biocompatibility	Test in accordance with ISO 10993	Test in accordance with ISO 10993	Test in accordance with ISO 10993	Same
Cytotoxicity	Yes	Yes	Yes	Same
Irritation	Yes	Yes	Yes	Same
Sensitization	Yes	Yes	Yes	Same
Single Use	Yes	Yes	Yes	Same
pH range	6.5-7.5	4.5-6	4-5	Although the pH of the subject device is a little different from predicate device, but the difference is slight, and it is close to the pH value of human skin surface, the pH is closed to 7 (neutral). So the slight differences in description will not raise any safety or effectiveness issue.
Impedance	0.2K Ohm or less	0.5K Ohm or less	80±10 Ohm	The value of impedance of the subject device is a little bigger than the predicate device (K192606), but much less than the

				predicate device (K111717). No new questions of safety or effectiveness are raised.
Conductivity	18.0±0.5 mS/cm	-	2 mS/cm	The subject device has a higher value of conductivity comparing to the predicate device (K190050), this is an advantage, as the gel results to be more conductive than the predicate device. Considering that, no new questions of safety or effectiveness are raised.
Characteristics	Salt Base Non-irritating Non toxic	Salt Base Non-irritating Non toxic	Salt Base Non-irritating Non toxic	Same

All the differences do not affect the safety and effectiveness of the subject device which is concluded after all the required testing, so there are no safety and effectiveness issues relating to the subject system.

Table 2 Compares features and specifications of the GT5 conductive & abrasive gel under review to the predicates Model 1700 HydroPrep and NuPrep.

Feature	GT5 conductive & abrasive gel (this submission)	Model 1700 HydroPrep	NuPrep	Comparison

510(k) number	-	K970694	K885306 510(K) Exempt	-
Product Code	GYB	GYB	DRX	Same
Indications for use	GT5 conductive & abrasive gel is intended for use in clinical and research EEG/EP recordings from humans. It can be not only used as skin-prep gel to abrade the skin surface lightly in order to reduce impedance (resistance to alternating current) efficiently, but also used as the conductor between the scalp and the external electrodes to reduce impedance between the electrode surface and the skin. GT5 conductive & abrasive gel is not intended for use with stimulating electrodes.	HydroPrep and Nuprep are skin preparation materials that are design for use by EEG Technicians. Both substances are applied to the skin surface with a cotton swab in order to reduce skin impedance and increase signal quality recorded with EEG electrodes. HydroPrep is not intended for use with stimulating electrodes.	Abrasive skin prepping gel intended for use when a reduction of skin impedance would enhance a test result e.g.: EEG exams, evoked potential procedures, ECG stress tests, cardiac rehabilitation monitoring, and cardiac catheter monitoring exam procedures.	The core of the "indications for use" of the subject device is the same to predicate devices, which is to reduce the impedance to the skin without affecting the use of EEG equipments. The slight differences in description will not raise any safety or effectiveness issue.
Regulation Name	Media, Electroconductive	Media, Electroconductive	Media, Electroconductive	Same
Regulation Number	882.1275	882.1275	870.2360	Same
Environment of use	Electrophysiological	Not publicly available	Not publicly available	-
Intended user	Neurologists	Not publicly available	Not publicly available	-
Target patient	Adult and children	Not publicly available	Not publicly available	-

Where used	Topically on intact skin	Not publicly available	Topically on healthy, intact skin	Same
Thickening agent	Sodium Carboxymethyl cellulose, Glycerin	Not publicly available	Sodium Polyacrylate, 1,2-Propanediol	Equivalent to predicates
Composition	Glycerin, Sodium chloride, Water, Methylparaben, Propylparaben, Sodium Carboxymethyl cellulose, Alkyl indican, Aluminum Oxide	Not publicly available	Water, Aluminum Oxide, 1,2-Propanediol, Sodium Polyacrylate, Methylparaben, Propylparaben, FD&C Blue 1, FD&C Red 40, FD&C Yellow 5	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, preservative, abrasive particles) in the process of producing the gel, so these differences do not raise different issue of safety or effectiveness.
Abrasive particle	Aluminum Oxide	Not publicly available	Aluminum Oxide	Same
Sterilization method	Provide non sterile	Not publicly available	Not publicly available	-
Shelf-life	3 years	Not publicly available	3 years	Same
Chemical Safety	No OSHA PEL	Not publicly available	No OSHA PEL	Same
Preservative	Methylparaben, Propylparaben	Not publicly available	Methylparaben, Propylparaben	Same
Biocompatibility	Test in accordance with ISO	Not publicly available	Not publicly available	-

	10993			
Single Use	Yes	Yes	Yes	Same
pH range	6.5-7.5	Not publicly available	Not publicly available	-
Impedance	0.2 K Ohm or less	Not publicly available	Not publicly available	-
Conductivity	18.0±0.5 mS/cm	Not publicly available	Not publicly available	-
Characteristics	Salt Base Non-irritating Non toxic	Not publicly available	Non toxic	Same

All the differences do not affect the safety and effectiveness of the subject device which is concluded after all the required testing, so there are no safety and effectiveness issues relating to the subject device.

7. Performance Testing

The safety and effectiveness of the GT5 conductive & abrasive gel were established and the substantial equivalence determination was supported by a series of performance testing, including biocompatibility testing, shelf life testing, and physical property testing.

Biocompatibility

The biocompatibility evaluation was conducted within the risk management framework and in compliance with ISO 10993 standards. This biocompatibility evaluation establishes the biological safety for the GT5 conductive & abrasive gel.

Shelf life testing

The aim of this test was to validate the shelf life of 3 years through an accelerated aging procedure according to the ASTM F1980-16 “Standard guide for accelerated aging of sterile barrier system for medical devices”).
Pass/fail criteria was fixed at the beginning of the test and all the results of the parameters evaluated (appearance, color, odor, pH, impedance and conductivity) comply with the pass/fail criteria.

Physical property testing

GT5 conductive & abrasive gel is tested internally for appearance, color, odor, pH, impedance and conductivity on a regular basis.

8. CONCLUSION

The device comparison and the results of the above listed performance testing indicate that the GT5 conductive & abrasive gel is substantially equivalent to the predicate devices, and the minor differences does not raise any different issues of safety or effectiveness.