September 15, 2023

Premier North America Inc.
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No. 19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K220735
Trade/Device Name: Avologi Gel Primer (Model: Av25)
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: August 17, 2023
Received: August 17, 2023

Dear Doris Dong:

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)*
K220735

Device Name
Avologi Gel Primer

Indications for Use *(Describe)*
The Avologi Gel Primer is intended to be used with Luminice device to improve skin conductivity

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

[As required by 21 CFR 807.92]

**1. Submission Information**

| | |
|---|---|
| 510(k) Number: | K220735 |
| Date: | August 17, 2023 |
| Type of 510(k) Submission: | Traditional 510(k) |
| Basis for 510(k) Submission: | New device |
| Owner: | Premier North America Inc.<br>3301 SW 42ND ST., FORT LAUDERDALE, FL 33312-6828, USA<br>Tel: 404-4928133-11<br>E-mail: Premiershai@Premierna.Com |
| Contact: | Doris Dong<br>[Consultant, from Shanghai CV Technology Co., Ltd.]<br>Add: Room 602, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China<br>E-mail: doris.d@ceve.org.cn<br>Tel: 86 21-31261348 / Fax: 86 21-57712250 |

**2. Device Description**

| | |
|---|---|
| Proprietary Name: | Avologi Gel Primer |
| Model: | Av25 |
| Regulation Name: | Electroconductive Media |
| Common Name: | Electroconductive Gel |
| Device Classification Name: | Media, Electroconductive |
| Regulation Number: | 21 CFR 882.1275 |
| Product Code: | GYB |
| Device Class: | II |
| Review Panel: | Neurology |
| Device Description: | The Avologi Gel Primer is a clear, viscous and chloride-free formulation. The gel is to be applied to the area under an electrode to reduce the impedance of the contact interface between the electrode surface and the skin. |
| Indications for use: | The Avologi Gel Primer is intended to be used with Luminice device to improve skin conductivity. |

**3. Predicate device Information**

| | |
|---|---|
| Predicate 510(k) Number: | K161654 |
| Marketing clearance date: | December 30, 2016 |
| Product name: | NuFACE Gel Primer |
| Manufacturer: | Carol Cole Company |

**4. Reference device Information**

| | |
|---|---|
| Reference510(k) Number: | K200402 |
| Marketing clearance date: | November 25, 2020 |
| Product name: | DR-HO'S Electro Therapy Conductive Gel |
| Manufacturer: | Guangzhou Xinbo Electronic Co., Ltd. |

| | |
|---|---|
| Reference510(k) Number: | K190050 |
| Marketing clearance date: | July 19, 2019 |
| Product name: | Tech Dots -Conductive gel |
| Manufacturer: | Spes Medica S.r.l. |

**5. Substantial Equivalence to Predicate device**

The proposed device Avologi Gel Primer has the same, or similar, technological characteristics as the predicate device NuFACE Gel Primer.

| Parameters | New Device | Predicate Device | Reference Device 1 | Reference Device 2 | Comparison |
|---|---|---|---|---|---|
| 510(k) Number | K220735 | K161654 | K200402 | K190050 | -- |
| Device name | Avologi Gel Primer | NuFACE Gel Primer | DR-HO'S Electro Therapy Conductive Gel | Tech Dots -Conductive gel | -- |
| Model | Av25 | / | DHGEL | / | -- |
| 510(k) Owner | Premier North America Inc. | Carol Cole Company | Guangzhou Xinbo Electronic Co., Ltd. | Spes Medica S.r.l. | -- |
| Regulation Number | 21CFR 882.1275 | 21CFR 882.1275 | 21CFR 882.1275 | 21CFR 882.1275 | SE |
| Regulation Name | Electroconductive Media | Electroconductive Media | Electroconductive Media | Electroconductive Media | SE |
| Regulatory Class | Class II | Class II | Class II | Class II | SE |
| Product Code | GYB | GYB | GYB | GYB | SE |
| Regulation Medical Specialty | Neurology | Neurology | Neurology | Neurology | SE |
| Intended Use | The Avologi Gel Primer is intended to be used with Luminice device to improve skin conductivity. | The NuFACE Gel Primer is intended to be used with NuFACE microcurrent devices to improve skin conductivity. | 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. | 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. | SE |
| Use | Over-the-Counter cosmetic use | Over-the-Counter cosmetic use | Over-the-Counter use | Prescription use | SE |

| | | | | | |
|---|---|---|---|---|---|
| Environment of use | Home | Home | Home | Hospital | SE |
| Target population | Adults 18 years of age or older | Adults 18 years of age or older | Not publicly available | Adult and children | SE |
| Where used | Topically on intact skin | Topically on intact skin | Intact Skin | Topically on intact skin | SE |
| Sterilization | Non-sterile | Non-sterile | Non-sterile | Non-sterile | SE |
| Color | Colorless | Colorless | Not publicly available | Not publicly available | SE |
| Appearance | Clear | Clear | Clear | Clear | SE |
| Odour | Odourless | Odourless | Odourless | Odourless | SE |
| Volume | 3.38fl.oz | 2 fl.oz. and 5 fl.oz. tube | Not publicly available | Not publicly available | SE |
| Weight(g) | 170 - 200 | Not publicly available | 250g / bottle | 0.14 ± 0.01 g per Dot | Note 1 |
| Specific gravity | 0.900 - 1.100 | Not publicly available | Not publicly available | Not publicly available | |
| Viscosity(cps) | 30000-80000 | Not publicly available | Not publicly available | Not publicly available | |
| pH | 5.0-7.0 | 6.0-7.0 | 7.0 - 7.5 | 4.1 ± 0.1 | |
| Biocompatibility | Complies with ISO 10993-5 and ISO 10993-10 | Complies with ISO 10993-5 and ISO 10993-10 | Complies with ISO 10993-5 and ISO 10993-10 | Complies with ISO 10993-5 and ISO 10993-10 | SE |
| Chemical Safety | Non-OSHA PEL | Non-OSHA PEL | Non-OSHA PEL | Non-OSHA PEL | SE |
| Conductive material | Salt (Magnesium Sulfate) | Salt (Magnesium Sulfate) | Purified water with Sodium hydroxide | Salt (NaCl) | SE |
| Impedance | 154Ω±10% | Not publicly available | 500Ω | 80 ± 10 Ohm | SE |
| Shelf-life | 3 years | Not publicly available | 2 years | 3 years | Note 2 |
| Gel composition | Deionized water, Propanediol, Hydrolyzed Hyaluronic Acid, Tremella Fuciformis Sporocarp Extract, Bentaine Glycerin, magnesium sulfate, carbomer, hydroxyethylcellulose, ethylhexylglycerin, potassium | Water/Aqua/Eau, Propanediol, Hydrolyzed Hyaluronic Acid, Tremella Fuciformis Sporocarp Extract, Bentaine Glycerin, magnesium sulfate, carbomer, hydroxyethylcellulose, ethylhexylglycerin, potassium | Purified water (solvent); Carbopol (gel forming); Glycerin (Moisturizing); Sodium hydroxide (Buffering); Triclosan (preservative) | Water, Glycerol (vegetable origin), Polyacrylate copolymer (proprietary), Potassium chloride | SE |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | sorbate, Caprylyl Glycol, phenoxyethanol, sodium hydroxide | sorbate, Caprylyl Glycol, phenoxyethanol, sodium hydroxide | | | |
| Conductivity (mS/cm) | | 2-5 | 3.38 | 2 | 2 | SE<br>Note 3 |
| Microbiological growth | Total Aerobic Microbial Count (cfu/g) | ＜1.0E+02 | Not publicly available | Not publicly available | Not publicly available | SE<br>Note 4 |
| | Molds & Yeasts (cfu/g) | ＜10 | Not publicly available | Not publicly available | Not publicly available | |
| | Pseudomonas aeruginosa (cfu/g) | Absence | Not publicly available | Not publicly available | Not publicly available | |
| | Staphylococcus aureus (cfu/g) | Absence | Not publicly available | Not publicly available | Not publicly available | |
| | Escherichia coli (cfu/g) | Absence | Not publicly available | Not publicly available | Not publicly available | |
| | Candida albicans (cfu/g) | Absence | Not publicly available | Not publicly available | Not publicly available | |
| **Conclusion of Substantial Equivalence to the Predicate Device:** | | | | | | |

Note 1:
The proposed device differs from the predicate device in pH, volume, weight, specific gravity, viscosity, and packaging. But these do not affect the performance of the product, and the packaging compatibility has been tested. Therefore, these differences will not raise any issues of safety or effectiveness.

Note 2:
Although the impedance and shelf life of the predicate device are not publicly available, the proposed device performed 3 years real-time stability testing and impedance testing. The impedance of the proposed device is 154Ω±10%, the impedance of 510K clearing number K200402 is 500Ω, which is larger than that of the proposed device; the impedance of K190050 is 80±10Ω, which is smaller than that of the proposed device. Therefore, these differences will not raise any issues of safety or effectiveness.

Note 3:
Conductivity of our device is similar to the predicate device. Furthermore, our device has a higher value of conductivity comparing to some cleared devices (2mS/cm), which will be more conductive. So no issues of safety or effectiveness will be raised.

Note 4:
Both our device and the predicate device are non-sterile, we have conducted microbiological growth test per USP61/62, and the biocompatibility test results indicated that the skin had no adverse reaction to microbiological growth of the proposed device. Therefore, the difference will not raise any issues of safety or effectiveness.

**6.Summary of Non-clinical Testing**

The safety and effectiveness of the Avologi Gel Primer 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**

In vitro Cytotoxicity Test:The test article were non cytotoxicity to L929 cells.
Intracutaneous Reactivity Test:The test article induce negligible irritation in a rabbit intracutaneous test.
Skin Sensitization Test:The test article showed no significant evidence of causing skin sensitization in the guinea pig.

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 Avologi Gel Primer.

- ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)

- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)
- ISO 10993-23 First edition 2021-01,Biological evaluation of medical devices - Part 23: Tests for irritation.(Biocompatibility)

**Shelf life testing**

The shelf life of Avologi Gel Primer is 3 years.To ensure the shelf life of Avologi Gel Primer, we have performed the real-time stability testing (3 years). The result demonstrates that the Avologi Gel Primer meet intended specification.

**Physical property testing**

- Microbiological growth testing

Microbiological Complies with the classification “Satisfactory” for the parameters tested.

- Packaging compatibility testing

Packaging compatibility test according to organoleptic and chemical tests.The test carried out viscosity determination, specific gravity determination, pH determination, weight determination. Test results Sensory tests of all samples did not show any differences.

- Conductivity testing

Test results all the samples pass conductivity test.

- Stability testing

Color, odor, appearance and impedance are as specified and equivalent to the predicate device.

**7.Conclusion**

The conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.The device comparison and the results of the above listed Non-clinical Testing indicate that the Avologi Gel Primer is substantially equivalent to the predicate devices, and the minor differences does not raise any different issues of safety or effectiveness.The subject device Avologi Gel Primer is substantial Equivalent to the predicate device K161654.