February 7, 2020

Nihon Kohden Corporation
% Natalie Kennel
Quality & Regulatory Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, California 92129

Re: K191975
Trade/Device Name: Elefix V Paste for EEG & EMG
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive Media
Regulatory Class: Class II
Product Code: GYB
Dated: January 6, 2020
Received: January 8, 2020

Dear Natalie Kennel:

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,

Vivek Pinto, PhD
Director
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191975

Device Name
Elefix V Paste for EEG & EMG

Indications for Use *(Describe)*
Elefix V Paste for EEG & EMG is a conductive paste used with surface electrodes to lower skin-electrode impedance. It can be used with electrodes for EEG and EMG examination.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary – K191975

Sponsor: Nihon Kohden Corporation
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Tokyo, Japan 161-8560

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Date Prepared: February 6, 2020

## DEVICE INFORMATION:

Proprietary Name: Elefix V Paste for EEG & EMG
Common Name: Electroconductive Media
Classification: Class II
Product Code: GYB
Regulations: 21 CFR 882.1275
Classification Panel: Neurology

## PRODUCT DESCRIPTION:

The Elefix V Paste for EEG & EMG is the electroconductive media used with external electrodes to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin. The Elefix V Paste for EEG & EMG is an aqueous based material with Sodium Chloride as the conductive material combined with emulsifiers, humectants and preservatives. The Elefix V Paste for EEG & EMG has been designed to have increased stiffness and improved temperature resistance compared to its predecessor, the

predicate device. These changes allow the paste to stay in place better as desired by its users. The Elefix V Paste for EEG & EMG has a neutral pH compared to the slightly alkaline pH of the predicate.

The Elefix V Paste for EEG & EMG is available in two models: ZV-401E and ZV-181E. ZV-401E is a container filled with 400 g of the paste. ZV-181E is a tube filled with 180g of the paste.

The Elefix V Paste for EEG & EMG is intended to be used by qualified medical personnel within a medical facility. It can be used with electrodes for electroencephalography (EEG) and electromyography (EMG) examination.

## INDICATIONS FOR USE:

Elefix V Paste for EEG & EMG is a conductive paste used with surface electrodes to lower skin-electrode impedance. It can be used with electrodes for EEG and EMG examination.

For prescription use only

## PREDICATE DEVICES:

Table 1 contains information about the predicate device.

**Table 1 Predicate Device Information**

| 510(k) | Product | 510(k) Holder | Clearance Date |
|---|---|---|---|
| K860210 | Elefix EEG Electrode Cream | Nihon Kohden Corporation | 07/01/1986 |

## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 2 is a detailed comparison of the Elefix V Paste for EEG & EMG and its predicate Nihon Kohden Elefix EEG Electrode Cream (K860210). The Elefix V Paste for EEG & EMG has the same intended use, same intended population, and is the same or similar in most physical and chemical attributes. The chemical composition differences are primarily to remove some ingredients to increase the subject device's performance by increasing stiffness and temperature resistance. The subject device has more neutral pH than the predicate device. All other attributes are the same as the predicate device.

**Table 2 Comparison of the Elefix V Paste for EEG & EMG and its predicate**

| Characteristics | Elefix V Paste for EEG & EMG (this submission) | Nihon Kohden Elefix EEG Electrode Cream (K860210) | Comparison |
|---|---|---|---|
| Classification Panel | Neurology | Neurology | Same |
| Classification Name | Electroconductive media (21 CFR 882.1275) | Electroconductive media (21 CFR 882.1275) | Same |
| Regulatory Class | II | II | Same |
| Product Code | GYB | GYB | Same |
| Intended Use | ElefixV Paste for EEG & EMG is the electroconductive media used with external electrode to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin. | Elefix is the electroconductive media used with external electrode to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin. | Same intended use. |
| Indications for Use | Elefix V Paste for EEG & EMG is a conductive paste used with surface electrodes to lower skin-electrode impedance. It can be used with electrodes for EEG and EMG examination. | The Elefix EEG Cream is designed for attaching Nihon Kohden electrodes in EEG measuring. | Substantially equivalent. The subject device has the same intended use as the predicate device. There is no difference in functionality required of electroconductive media between EEG and EMG. Therefore, this difference does not raise different issue of safety or effectiveness. |
| Patient population | Adults and pediatrics | Adults and pediatrics | Same |

| Characteristics | Elefix V Paste for EEG & EMG (this submission) | Nihon Kohden Elefix EEG Electrode Cream (K860210) | Comparison |
|---|---|---|---|
| Composition (function of ingredient) | · Water (solvent)<br>· Oleth-30 (emulsifier)<br>· PEG-60 hydrogenated castor oil (emulsifier)<br>· Calcium carbonate (opacifier)<br>· Petrolatum (base)<br>· Glycerin (humectant)<br>· Sodium chloride (conductive material)<br>· Propylene glycol (humectant)<br>· PEG-40 hydrogenated castor oil (emulsifier)<br>· Cetyl alcohol (emollient)<br>· BHT (antioxidant)<br>· Methylparaben (preservative)<br>· Propylparaben (preservative) | · Water (solvent)<br>· Polyoxyethylene oleylether phosphate (emulsifier)<br>· Glycerin (humectant)<br>· Calcium carbonate (opacifier)<br>· Liquid petrolatum (base)<br>· Propylene glycol (humectant)<br>· Lanolin alcohol (emollient)<br>· Sodium chloride (conductive material)<br>· Sodium hydroxide (pH control)<br>· Polyoxyethylene hydrogenated lanolin (emulsifier)<br>· Coconut fatty acid diethanolamide (emulsifier)<br>· Polyoxyethylene stearylether (emulsifier)<br>· Oleth-30 (emulsifier)<br>· BHT (antioxidant)<br>· Methylparaben (preservative)<br>· Propylparaben (preservative) | Substantially equivalent.<br>Although the subject device and the predicate device have some difference in composition, the subject device includes the same or substantially equivalent ingredients as the predicate The ingredients included in the subject device have functionality same as the ingredients included in the predicate. These differences do not raise different issue of safety or effectiveness. |
| Patient Contact | Intact Skin | Intact Skin | Same |
| Single-use | Yes | Yes | Same |
| Sterile | Non-Sterile | Non-Sterile | Same |
| Biocompatibility | Complies with ISO 10993-1 | Complies with ISO 10993-1 | Same |
| Shelf Life | 24 Months | 24 Months | Same |
| Impedance | 1 kΩ or less at 50Hz | 1 kΩ or less at 50Hz | Same |
| pH | 6.5 to 8.5 | 8.5 to 9.5 | Different<br>Although the subject device and the predicate device have the difference in pH, the subject device is closer to neutral pH. This difference does not raise different issue of safety or effectiveness. |
| Conductivity | 1.04 S/m | 1.08 S/m | Substantially equivalent |

| Characteristics | Elefix V Paste for EEG & EMG (this submission) | Nihon Kohden Elefix EEG Electrode Cream (K860210) | Comparison |
|---|---|---|---|
| Stiffness (using curdmeter) | 35 to 50 | 25 to 50 | Different<br>By design, the subject device is stiffer than the predicate device. The stiffness range for the subject device is tighter than the predicate. This difference does not raise different issue of safety or effectiveness. |
| Temperature Resistance | Yes | NA | Different<br>By design, the subject device is stiffer than the predicate device to provide increased temperature resistance compared to the predicate device. This difference does not raise different issue of safety or effectiveness. |

## PERFORMANCE DATA

The safety and effectiveness of the Elefix V 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. The physical properties testing included impedance testing, pH testing, stiffness testing and temperature resistance testing were conducted across the environmental operating range for the Elefix V Paste for EEG & EMG. The subject device met all acceptance criteria which were informed by the predicate device. There are minor differences in pH, stiffness, and temperature resistance of the Elefix V Paste for EEG & EMG compared to the predicate device. These differences are by design to improve product performance and do not raise different issues of safety or effectiveness.

## BIOCOMPATIBILITY

The biocompatibility evaluation was conducted within the risk management framework and in compliance with ISO 10993 standards. This evaluation of the device included relevant data sources related to biological safety of finished device testing, component material history of safe biological use and testing, and where applicable, safe previous use in previously cleared product. This biocompatibility evaluation establishes the biological safety for the Elefix V Paste for EEG & EMG.

## SHELF LIFE TESTING

The Elefix V Paste is a single use, non-sterile material.

The Elefix V Paste for EEG & EMG has been validated for product shelf life. In use stability has been validated for the product's ability to withstand an open container condition for an extended time at worst case operating environmental conditions of high temperature and low humidity.

## BENCH TESTING

The Elefix V Paste for EEG & EMG has been subjected to design verification and validation testing for operational performance for pH, impedance, stiffness, and temperature resistance across its stated environmental operating and storage range.

## CONCLUSION

The device comparison and the results of the above listed performance testing indicate that the Nihon Kohden Elefix V Paste for EEG & EMG is substantially equivalent to the predicate device, Nihon Kohden Elefix EEG Electrode Cream (K860210), and the minor differences raises no different issues of safety or effectiveness.