



October 16, 2023

TOP-RANK Health Care Co., Ltd.  
% Heather Wang  
Consultant  
Microkn Medical Technology Service (Shanghai) Co., Ltd.  
Room 901, No. 889, Pinglu Road, Jing'an District,  
Shanghai (Shanghai Jing'an HUAFU Center)  
Shanghai, Shanghai 200435  
China

Re: K232020  
Trade/Device Name: Iontophoresis Electrodes  
Regulation Number: 21 CFR 890.5525  
Regulation Name: Iontophoresis Device  
Regulatory Class: Class II  
Product Code: EGJ  
Dated: August 18, 2023  
Received: August 18, 2023

Dear Heather Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto: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 Rehabilitation Devices

OHT5: Office of Neurological  
and Physical Medicine Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

## Indications for Use

510(k) Number (if known)  
K232020

Device Name  
Iontophoresis Electrodes

Indications for Use (Describe)

Iontophoresis Electrodes are intended to be used to introduce soluble salts and other drugs into the body as an alternative to hypodermic injection.

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**

### **1. Contact information**

#### **1.1. Applicant**

Applicant Name: Top-Rank Health Care Co., Ltd.

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#### **1.2. Consultant**

Company: Microkn Medical Technology Service (Shanghai) Co., Ltd.

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(Shanghai Jing'an HUAFU Center)

Contact Person: Heather. Wang

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### **2. Device information**

- Common Name: Iontophoresis Electrodes
- Model(s): ION-T01, ION-T02, ION-T03, ION-T04, ION-T05
- Classification: II
- Product Code: EGJ
- Regulation Number: 21CFR 890.5525

### **3. Indications for Use**

Iontophoresis Electrodes are intended to be used to introduce soluble salts and other drugs into the body as an alternative to hypodermic injection.

### **4. Legally Marketed Predicate Device**

Product name: Iontophoresis Drug Delivery Electrodes

510(k) Number: K040495

Product Code: EGJ

Manufacture: NAIMCO, INC.

### **5. Description of the device**

The proposed device is indicated for the administration of soluble salts or other drugs into the body for medical purposes. The Iontophoresis Electrodes utilize adhesive electrodes have both anode and cathode electrodes that adhere to the skin. The electrodes may either be connected by leads (wires) to a separate controller Forming a current loop. The portion of the active electrode that contacts the skin also has a drug/solution reservoir. End users saturate the

reservoir with the ionic solution to be delivered. The reservoir contacts the electrode and the drug/solution is delivered to the patient transdermally.

Five models (Small, Medium, Large, Butterfly and Return Electrode) are included in this series products, and they have the same intended purposes, working theories and specifications.

The main components of proposed device shown in **Table 1**.

**Table 1 Main Components of Proposed Device**

<b>Component name</b>	<b>Description</b>	<b>Applied to</b>
Conductive button (Upper)	It serves as a connecting component to the output terminal of the controller, completing mechanical and electrical connection functions	ALL Models
Conductive button (Lower)	Conductive button (Lower) is used in conjunction with the upper part and mechanically riveted to achieve a firm connection between materials	ALL Models
POLY film layer	It is a thin film made of polyethylene material that is used to support the surface of the product and achieve electrical insulation functions with other internal components	ALL Models
Conductive carbon film layer	It is a conductive film made of PU material and carbon material, which realizes the transmission and uniform distribution of current by connecting with metal buckle and covering gel layer in a large area	ALL Models
Self-adhesive GEL layer	It is used to adhere return electrode to the skin surface, and its conductive properties can form a conductive circuit between the controller and the body surface skin	ALL Models
GEL Protective layer	It is used to store return electrode and has isolation and protection effects on Self-adhesive GEL	ALL Models
Foma layer	It is used to adhere active drug delivery electrode to the skin surface, at the same time, it ensures a firm fit and prevents the outflow of drug/solution	ALL Models
AgAgCl film layer	AgAgCl is mainly used to alleviate the electrolytic reaction of water, thereby preventing pH related corrosive skin reactions	ALL Models
drug/solution reservoir layer	It is a medical porous material with good water absorption and is used for temporary storage of drug/solution	ALL Models
Release paper layer	Used for long-term storage of active drug delivery electrodes to ensure stable electrode performance	ALL Models

## **6. Non-Clinical Test conclusion**

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1 Medical electrical device Part1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation

## **7. Clinical Test Conclusion**

No clinical study is included in this submission.

## **8. Predicate Devices**

Product name: Iontophoresis Drug Delivery Electrodes

510(k) Number: K040495

Product Code: EGJ

Manufacture: NAIMCO, INC.

## 9. Substantially Equivalent (SE) Comparison

The Iontophoresis Electrodes has been carefully compared to legally marketed devices with respect to intended use, configuration, principle of operation (**Table 2**), performance specifications (**Table 3**).

**Table 2 General Comparison**

Item	Proposed Device	Predicate Device	Remark
	Iontophoresis Electrodes (K232020)	Iontophoresis Drug Delivery Electrodes (K040495)	
Product Code	EGJ	EGJ	Same
Regulation Number	21CFR 890.5525	21 CFR 890.5525	Same
Indications for Use	Iontophoresis Electrodes are intended to be used to introduce soluble salts and other drugs into the body as an alternative to hypodermic injection.	Iontophoresis Drug Delivery Electrodes are intended to be used to introduce soluble salts and other drugs into the body as an alternative to hypodermic injection.	Same
Patient Population	With patients requiring iontophoresis treatment	With patients requiring iontophoresis treatment	Same
Usage environment	Hospitals, medical clinics	Hospitals, medical clinics	Same

**Table 3 Performance Comparison**

Item	Proposed Device	Predicate Device	Remark
	Iontophoresis Electrodes	Iontophoresis Drug Delivery Electrodes	
Design (Electrode Size)	ION-T01(69×69mm), ION-T02(82×82mm), ION-T03(88×88mm), ION-T04(84×94mm), ION-T05(64×64mm)	Small(2.75×2.75inch), Medium(3.25×3.25inch), Large (3.5×3.5inch), Butterfly(3.35×3.75inch), Return Electrode (2.5×2.5inch)	<b>Same (Note1)</b>
Main materials	Silver/Silver Chloride (Ag/AgCl) Buffering Agent; PU Conductive carbon film	Silver/Silver Chloride (Ag/AgCl) Buffering Agent; PU Conductive carbon film	Same
Anatomical sites	For body surface skin	For body surface skin	Same
Working mode	Must be used as a complete set Consists of an active drug delivery electrode and a passive return electrode.	Must be used as a complete set Consists of an active drug delivery electrode and a passive return electrode.	Same
Compatibility with other	Designed for use with iontophoresis devices only.	Designed for use with iontophoresis devices only.	Same

Item	Proposed Device	Predicate Device	Remark
	Iontophoresis Electrodes	Iontophoresis Drug Delivery Electrodes	
devices			
Impedance	2MΩ~10MΩ	2MΩ~10MΩ	Same
System current	4.0mA	4.0mA	Same
Maximum Dosage	80 mA-min	80 mA-min	Same
Fill Volume	1.5cc (ION-T01), 2.5cc (ION-T02), 4.0cc (ION-T03), 2.0cc (ION-T04)	1.5cc (201-400), 2.5cc (201-401), 4.0cc (201-402), 2.0cc (201-403)	Same

**Note 1**

The new device Iontophoresis Electrodes is substantial equivalence as the predicate device K040495. The differences in Dimensions, model are the differences in design requirements between different devices, which not affect the safety performance of the device, and the new device passed Safety testing, so these differences will not cause any safety and effectiveness issues. Considering the same intended use, Working mode and Product performance ect, they are substantial equivalence.

Safety comparison has been done to validate the EMC, biocompatibility

specification and safety of the device (Table 4).

**Table 4 Safety Comparison**

<b>Item</b>	<b>Proposed Device</b>	<b>Predicate Device</b>	<b>Remark</b>
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Skin sensitization	No evidence of sensitization	No evidence of sensitization	Same
Irritation	No evidence of irritation	No evidence of irritation	Same
EMC, Electrical Safety			
Electrical safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

### **10.Substantially Equivalent (SE) Conclusion**

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.