

**Section 4**

**Premarket Notification [510(k)] Summary**

[As required by CFR 21 807.92(c)]

510k = K090198

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**Date:** May 7<sup>th</sup>, 2009<sup>2</sup>  
**Submitter:** Wuxi Jiajian Medical Instrument Co., Ltd  
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JUN 23 2009

**Device Summary:**

**Trade Name:** Jiajian Self- adhesive Electrode  
**Common or Usual Name:** Cutaneous electrode  
**Classification Name:** Electrode, cutaneous  
**Product Code:** GXY  
**Regulation Number:** 882.1320  
**Medical Specialty:** Neurology  
**Device Class:** II  
**Device Description:** Jiajian branded Self-adhesive Electrodes, wire type, are non-sterile flexible structures, composed of materials commonly used in this application:

First layer: Nonwoven fabric tape

Second layer: Electrically conductive carbon cloth (ValueTrove<sup>®</sup> Carbon, K970426)

Third layer: Biocompatible conductive hydrogel coupling media (ValueTrove<sup>®</sup> GEL, K970426), which has passed the required skin sensitivity testing criteria as specified in ISO 10993-10 and cytotoxicity testing criteria as specified in ISO 10993-5.

The electrodes are designed for single patient / multiple application use. It can be used for low-frequency or medium-frequency nerve or muscle stimulators, as the conduction film adhered to body skin.

There are six shapes of round, rectangle, oval, gourd, butterfly and saddle of the electrodes.

For the electrical connection, Jiajian provides wire type:

Lead wire assembly - at least 40mm long wire with 2.5mm diameter female socket, connected to one side of the wire.

The lead wire assembly is in compliance with the requirements of FDA performance standard 21 CFR Part 898 by testing under IEC 60601-1, subclause 56.3(c).

**Indications for use:** The self-adhesive electrode is intended to be used to apply electrical stimulation current to the patient's skin.  
Example electrical stimulations for current applications of the electrodes are: TENS and EMS

**Substantial Equivalence Information:**

**1) Predicate Device 1:**

510(k) Number: K080276  
Marketing clearance date: August 4<sup>th</sup>, 2008  
Product name: Self-Adhesive electrodes  
Manufacturer: Cathay healthcare equipment manufacturing, Inc

**2) Comparison with predicate device**

**Similarities:**

- 1) Similar materials composition and intended use;
- 2) Both are non-sterile and reusable;
- 3) Both were established biocompatibility on standards of ISO 10993-5-1999: Tests for cytotoxicity: In vitro methods; ISO 10993-10: 2002: Tests for Irritation and Sensitization
- 4) Both electrodes distributes electrical current evenly.

**Differences:** For intended use, the Self-Adhesive electrodes with K080276 is also intended to be used to record physiological signals, while Jiajian Self-adhesive Electrode is not.

**3) Conclusion:**

JIAJIAN MEDICAL considers Jiajian Self- adhesive Electrode to be as safe and effective as the predicate device of Self-Adhesive electrodes (K080276).

**1) Predicate Device 2:**

510(k) Number: K020735  
Marketing clearance date: July 12th, 2002  
Product name: SOF-PACH™ Reusable Neurostimulation Electrodes  
Manufacturer: CATHAY INTERNATIONAL LTD.

**2) Comparison with predicate device**

**Similarities:**

- 1) Similar materials composition and structures;
- 2) Similar intended use;
- 3) Both are non-sterile and reusable;
- 4) Both were established biocompatibility on standards of ISO 10993-1
- 5) Both are safe and effective by impedance and adhesive testing
- 6) Both lead wires conform to FDA 21 CFR Part 898.

**Differences:** As to the first layer of the material of the electrode, OF-PACH™ Reusable Neurostimulation Electrodes use more kinds of materials, while Jiajian Self- adhesive Electrodes only use nonwoven fabric

**3) Conclusion:**

JIAJIAN MEDICAL considers Jiajian Self- adhesive Electrode to be as safe and effective as the predicate device of SOF-PACH™ Reusable Neurostimulation Electrodes (K020735).



JUN 23 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Wuxi Jiajian Medical Instrument Co., Ltd.  
c/o Doris Dong  
Technical Manager  
Qinghong Rd., Ehu Town Xishan District  
Wuxi, Jiangsu  
China 214116

Re: K090198  
Trade/Device Name: Jiajian Self-Adhesive Electrode  
Regulation Number: 21 CFR 882.1320  
Regulation Name: Cutaneous Electrode  
Regulatory Class: II  
Product Code: GXY  
Dated: May 7, 2009  
Received: June 2, 2009

Dear Ms. 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. 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.

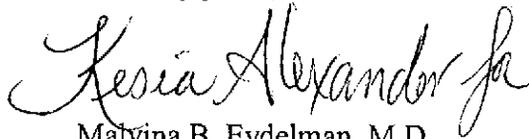
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

**Section 3**  
**Statement of Indications for Use**

510(k) Number (if known): K090198

Device Name: Jiajian Self- adhesive Electrode

**Indications for Use:**

The self-adhesive electrode is intended to be used to apply electrical stimulation current to the patient's skin.

Example electrical stimulations for current applications of the electrodes are:

TENS (Transcutaneous Electrical Nerve Stimulation)

EMS (Electrical Muscular Stimulation)

Prescription Use   
(Part 21 CFR 801 Subpart D)

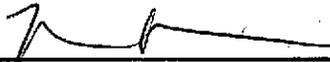
AND/OR

Over-The-Counter Use   
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

510(k) Number K090198