K080276

510(K) SUMMARY

AUG - 4 2008

[as required by 807.92(c)]

A. 510k Number:

B. Applicant:

Company name: **Cathay healthcare equipment manufacturing. Inc**

Address: **Taoyuan Village,Changtang Town, Shangyu City, Zhejiang Province, China**

Tel: +86 575 8259988

Fax: +86 575 8259977

C. Proprietary and Established Names: **Cathay healthcare equipment manufacturing. Inc**

D. Regulatory Information

-Product name: Self-Adhesive electrodes

-Classification: Class 2

-Product cord : GXY

-Regulation Number : 882.1320

E. Intended use

The electrotherapy electrodes are intended to be used to apply electrical stimulation current to the patient's skin or record physiological signals

F. Device Description

This type of electrode features a high density carbon mesh that evenly distributes current throughout the electrode surface. It connects to a TENS device through single or twin lead wire. Various standard sizes can be chosen. Any custom design can also be manufactured.

G. Substantial Equivalence Information

1. Predicate Device – K020735, K070612

-SOF-PACH Reusable Neurostimulation Electrodes/ TOP-RANK ADHESIVE ELECTRODE

-Classification : Class 2

-Product cord : GXY

-Regulation Number : 882.1320

2. Comparison with predicate

From the above clinical evidence, we can conclude that Clinical evidence is

demonstrated by way of

- Comparison chart of predicate device
- Experience from previous use
- Testing reports, analysis

Therefore, we need not perform clinical investigation.

And, the safety and performance of Adhesive Electrodes is verified.

Based on the above, we conclude that the Adhesive Electrodes are substantially equivalent to the marketed predicate device, and do not raise any new issues of safety or effectiveness.

H. Standard / Guidance Document Referenced (if applicable)

1)	ISO 9001	2000	Quality management system -requirements
2)	EN ISO 14971	2001	Medical devices — Application of risk management to medical devices
3)	EN 980	2003	Graphic Symbols for use in the labeling of medical device
4)	EN 1041	1998	Terminology, Symbols and Information with Medical Devices; Information supplied by the manufacturer with medical devices
5)	EN ISO 10993-5	1999	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity ISO 10993-5:1999; Supersedes EN 30993-5:1994
6)	EN ISO 10993-10	2002	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity ISO 10993-10:2002

I. Performance Characteristics (If/when applicable)

1. See the Exhibits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2008

Cathay Healthcare Equipment Manufacturing, Inc.
% Pats Corporation
Mr. Brandon Choi
Representative
Flemington Court, Suite 155
La Mirada, California 90638

Re: K080276
Trade/Device Name: Self-Adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: July 24, 2008
Received: July 29, 2008

Dear Mr. Choi:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: SELF-ADHESIVE ELECTRODES

Indications For Use: The electrotherapy electrodes are intended to be used to apply electrical stimulation current to the patient's skin or record physiological signals

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Milhouse

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080276