K103719

# 510(k) Summary

AUG 2 4 2011

**As Required by 21 section 807.92 ( c )**

**1-Submitter Name:** Everyway Medical Instruments Co., Ltd.
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**5-Contact Person:** Mr. Robert Tu (General Manager)
**6-Date summary prepared:** July 15th, 2011
**7- Official Correspondent:** Mansour Consulting LLC
**8- Address:** 845 Aronson Lake Court. Roswell, GA 30075 USA
**9- Phone:** 678-908-8180
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**11- Contact Person:** Jay Mansour, President
**12-Device Trade or Proprietary Name:** Lifecare HC-88 Series Conductive Garments
**13-Device Common or usual name:** Lifecare HC-88 Series Conductive Garments
**14-Device Classification Name:** Cutaneous electrode
**15-Substantial Equivalency** is claimed against the following device:

- TheraKnit Garment Cutaneous Electrodes from Neurotron Medical, Inc. 510k# K053214

**16-Description of the Device:**

The single-patient reusable and non-sterile Lifecare HC-88 Series Conductive Garments are cutaneous, flexible, conductive garment/fabric electrodes.
They are passive devices acting as interface between electrical stimulators (such as powered muscle stimulators, interferential devices, galvanic device and transcutaneous electrical nerve stimulators) and a patient's skin. The signal is transmitted from the conductive knob through the cloth of conductive garment to the surface of the patient's skin.
The Lifecare HC-88 Series Conductive Garments are used in conjunction with electrical stimulators both in the home and physical therapy setting, and can stimulate large or multiple. They are knitted in different shapes, as gloves, socks, kneecaps and wristlets/elbow guards, and in different sizes.

The Lifecare HC-88 Series Conductive Garments are constructed with four basic components (materials): a metal conductive snap terminal; cloth knitted together with Spandex and Stainless-steel yarns that twisted and composed by Stainless-steel and Nylon fibers. **The garments are not packaged with lead wire.**

Impedance testing evaluated by the "Resistance meter of electronic multimeter" to measure the impedances of all conductive garments are below 5 ohms between each centimeter and evaluated by the "oscilloscope measuring circuit" to measure the total impedance of all conductive garments are below 50 ohms" . Even after over 20 times washing, the impedance of Lifecare HC-88 Series Conductive Garments are still within specification.

The garments are not compatible with MRI spectrometry.

**17-Intended use of the device: (refer to FDA form attached)**

The Lifecare HC-88 Series Conductive Garments are used in conjunction with electrical stimulators both in the home and physical therapy setting, and can stimulate large or multiple. They are knitted in different shapes, as gloves, socks, kneecaps and wristlets/elbow guards, and in different sizes.

**18-Safety and Effectiveness of the device:**

This device is safe and effective as the predicate devices cited above as detailed within this submission. This type of device has been marketed and used in US for several years as Prescription use and proven to be safe and effective without side effects or complications generated from the use of the device itself.

**19-Biocompatibility of material:**

The material of Lifecare HC-88 Series Conductive Garments were evaluated and passed the evaluation of biocompatibility testing by SGS Taiwan Ltd.

- Cytotoxicity test (ISO 10993-5, SGS report No.UB/2010/50533),
- Skin irritation test (ISO 10993-10, SGS report No. UB/2010/50533A-01) and
- Skin sensitization test (ISO 10993-10, SGS report No. UB/2010/50533A-02)

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**20-Approximate surface area of each garment model:**

| REF.NO | SIZE | SURFACE AREA | Type |
|---|---|---|---|
| HC-884A | M(L21cm) | 450cm² | Glove |
| HC-885A | L(L24cm) | 580cm² | Glove |
| HC-886A | S(L18cm) | 330cm² | Glove |

| REF.NO | SIZE | SURFACE AREA | Type |
|---|---|---|---|
| HC-883 | (L33xW9cm) | 600cm² | Sock |

| REF.NO | SIZE | SURFACE AREA | Type |
|---|---|---|---|
| HC-881A | M(L18xW11cm) | 400cm² | Wristlet/Elbow |
| HC-881-1A | S(L18xW10cm) | 360cm² | Wristlet/Elbow |

| REF.NO | SIZE | SURFACE AREA | Type |
|---|---|---|---|
| HC-882A | M(L27xW14cm) | 760cm² | Kneecaps |
| HC-882-1A | S(L27xW10cm) | 540cm² | Kneecaps |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Everyway Medical Instruments Co., Ltd.
c/o Mr. Jay Mansour
Mansour Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

AUG 24 2011

Re: K103719
Trade/Device Name: Lifecare HC 88-Series Conductive Garments
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 1, 2011
Received: August 5, 2011

Dear Mr. Mansour:

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. 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); 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for 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

# Indications for Use

510(k) Number (if known):

Device Name: Lifecare HC-88 Series Conductive Garments

Indications For Use:

The Lifecare HC-88 Series Conductive Garments are cutaneous electrodes to be used with legally marketed electrical stimulators (such as powered muscle stimulators and transcutaneous electrical nerve stimulators).
The knitted garment electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact.

These body parts include hands (gloves), feet (socks), wrists / elbows (wristlets / elbow guards) and knees (kneecaps).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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