K120516

MAY 17 2012

510(k) Summary
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May 9, 2012

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Official Contact: Mirna DiPano– Director, Quality & Regulatory

Proprietary or Trade Name: LONG LIFE PAD™

Common/Usual Name: Cutaneous electrode

Classification Name/Code: GXY – electrode, cutaneous
CFR 882.1320
Class 2

Device: Long Life Pad™

Predicate Device: Well Life Healthcare Limited – Well-Life Self Adhesive Electrodes K082065

Device Description:
The LONG LIFE PAD™ is intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. These pads should be used only with the Omron Electrotherapy Pain Relief Unit, (PM3030) and applied on normal, healthy, dry, clean skin of adults.

The LONG LIFE PADs™ are non-sterile, disposable, laminated, flexible structures composed of the following three main construction layers from bottom to top:

- Polyester protective film,
- gel,
- carbon layer,
- non-skin contact polyethylene lamination layer
- snap connection

The electrodes are designed for single-patient/multiple application use. Because of the Adhesive's nature of the biocompatible hydrogel, no securing materials are required to secure the device to the patient's skin.

The pad patient contacting surface is a biocompatible hydrogel. The electrode has one connection point that is used to connect the stimulation device to the electrodes. This connection point is compatible only with the Omron PM3030.

Indications for Use:
The LONG LIFE PAD™ is intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. These pads should be used only with the Omron Electrotherapy Pain Relief Unit, (PM3030) and applied on normal, healthy, dry, clean skin of adults.

Environment of Use:
Clinics, hospital and home use environments

Contraindications
Do not use these pads for stimulation if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Summary of substantial equivalence
The LONG LIFE PAD™ was compared to the predicate Well-Life Self Adhesive Electrodes (K082065) as in the device comparison table below.

Device Comparison

	Well-Life Pad 510(k) K082065	Long Life Pad	Comparison
Indications for Use	The Well Life Self Adhesive Electrode/CM, FA, PU and SP series are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Well Life Self Adhesive Electrode / AP, CM, FA, PU and SP series are designed and intended to be used With marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation)	The LONG LIFE PAD™ is intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. These pads should be used only with the Omron Electrotherapy Pain Relief Unit, (PM3030) and applied on normal, healthy, dry, clean skin of adults.	Similar indications. The Long Life Pad is restricted to the Omron PM3030 stimulator (K110068)
Product Code	GXY	GXY	Identical
Prescriptive or OTC	Both	OTC	Similar
Environment Of use	Clinics, hospital and home use environments	Clinics, hospital and home use environments	Identical

	Well-Life Pad **510(k) K082065**	**Long Life Pad** **510(k) TBD**	**Comparison**
Patient Population	Adult	Adult	Identical
Conductive Interface	Biocompatible hydrogel	Biocompatible hydrogel	Identical
Construction & Materials	Bottom to top: • PET protective layer, • gel, • scrim layer, • carbon layer, • non-skin contact white foam layer • with snap connection	Bottom to top: • Polyester protective film, • gel, • carbon layer, • non-skin contact polyethylene lamination layer • with snap connection	Construction layers and materials are very similar.

Differences Between Other Legally Marketed Predicate Devices
The Omron Long Life Pad is viewed as substantially equivalent to the predicate device because: The Long Life Pad uses the same principal of operation as the predicate. The Long Life Pad uses similar materials. The Long Life Pad has approximately the same surface area. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications – The Long Life Pad and the predicate (Well-Life Self Adhesive Electrodes K082065) are intended for use as disposable, conductive adhesive interfaces between the patient's skin and an electrical stimulator.

Prescriptive – The Long Life Pad ™ is OTC as is the predicate.

Design and Technology – The Long Life Pad ™ has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The Long Life Pad ™ has equivalent specifications of performance as the predicate.

Materials – The patient contacting materials of the electrode has been tested in accordance to ISO 10993-1 and FDA Guidance as was the predicate.

Environment of Use – Same

Patient Population – The Long Life Pads are restricted to adults

Performance Testing -
We have performed bench tests and found that the Long Life Pads met all requirements specifications and "Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Cutaneous Electrode". The testing is comprised of

- Dispersion Test Protocol Report Summary
- Adhesion Test Protocol Report Summary
- Stability Testing (Storage Conditions)
- Stability Test Protocol Report (Shelf life)
- Stability Shipment Test Report Summary

Conclusion -
The LONG LIFE PAD™ is substantially equivalent to the predicate Well-Life Self Adhesive Electrodes (K082065) in indications for use, patient population, and environment for use, technology characteristics, specifications and performance.

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

Omron HealthCare, Inc.
c/o Mr. Paul E. Dryden
President, Regulatory Consultant for Omron
24301 Woodsage Drive
Bonita Springs, FL 34134

MAY 17 2012

Re: K120516
Trade/Device Name: Long Life Pad™
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 15, 2012
Received: February 21, 2012

Dear Mr. Dryden:

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

Enclosure

Indications for Use Statement

510(k) Number: K120516

Device Name: LONG LIFE PAD™

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Prescription Use (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use _X_** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M L B Nicholas

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

510(k) Number K120516