K070890

SUMMARY OF SAFETY AND EFFECTIVENESS
for Interferential Current Therapy, IF-100507

JUN 29 2007

DATE OF SUBMISSION:	February 15, 2007
SUBMITTER:	EVERLIFE MEDICAL EQUIPMENT CO., LTD. NO 58, FU-CHIUN ST. HSIN-CHU CITY, CHINA (TAIWAN) 30067 TEL: 886-3-5208829 FAX:886-3-5209783
ESTABLISHMENT REGISTRATION NO:	3004753827
OFFICIAL CONTACT:	Dr. JEN, KE-MIN NO 58, FU-CHIUN ST. HSIN-CHU CITY, CHINA (TAIWAN) 30067 TEL: 886-3-5208829 FAX:886-3-5209783
TRADE NAME:	EVERLIFE Interferential Current Therapy, IF-100507
COMMON/USUAL NAME:	Interferential Current Therapy
CLASSIFICATION NAME:	Interferential Current Therapy
REGULATION NUMBER:	Pre-Amendment
PREDICATED DEVICE:	APEX Interferential Current Therapy, IF-4000, K952683
INTENDED USE:	The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic acute pain.

Description of Device:	The IF-100507 generates small pulses of electrical current. Delivered along lead cables to electrodes placed on your skin, these pulses pass through the skin and activated underlying nerves. The relief from chronic and acute pain that the IF-100507 can provide results from this electrical stimulation.
Non-Clinical Tests Submitted:	The IF-100507 has been tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, and the particular requirements for safety of nerve and muscle stimulators. Accessories also meet safety requirements: 510(k) electrodes are specified, and the patient cable utilizes shrouded connectors to meet lead wire safety requirements. System level testing including waveform testing was performed in combination the IF-100507 stimulator.
Clinical Tests Submitted:	None
Conclusion:	As the product description and tests as above, the new device: EVERLIFE Interferential Current Therapy, IF-100507 is as safe and effective as, and the function in a manner equivalent to the predicate device: APEX Interferential Current Therapy, IF-4000, K952683. Thus the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Everlife Medical Equipment Co., Ltd.
% Ms. Shu-Chen Cheng
2064 Tamarin Drive
Columbus, Ohio 43235

Re: K070890
Trade/Device Name: EVERLIFE Interferential Current Therapy, Model IF-100507
Regulatory Class: Unclassified
Product Code: LIH
Dated: May 23, 2007
Received: May 23, 2007

Dear Ms. Cheng:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

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: K 070890

Device Name: EVERLIFE Interferential Current Therapy, IF-100507

Indications for Use :

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic acute pain.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070890