伊藤超短波株式会社 MANUFACTURERS & EXPORTERS
ITO CO,. LTD. *established in 1916*

3-3-3 TOYOTAMA-MINAMI, NERIMA-KU, TOKYO,176-0014 JAPAN

K081943

510(k) Summary:
Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination
Regarding the ES-130 Electro-Acupuncture Device

Submitter Name: ITO CO., LTD.
3-3-3 TOYOTAMA-MINAMI, NERIMA-KU
TOKYO, 176-0014 JAPAN
TEL: (+81) 3-3994-4619
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Contact Name: KENNETH L. BLOCK, RAC

Date Prepared: September 30, 2008

Proprietary Name: ES-130
Primary Product Code: BWK
Common Name: Stimulator, Electro-Acupuncture
Class: Unclassified

Predicate Devices: K051197: ACULIFE/Model SMW-01 (Inno-Health Technology, Inc.)
K840983: Pulselife Model PL2 (Pulse Life)
Pre-Amendment: Model WQ-10B (Danghua Electronic Instrument Factory)

Device Description:

ES-130 is a palm-size ELECTRO-ACUPUNCTURE DEVICE equipped with three independent output channels. This unit has incorporated similar features as the predicate devices such as:

- Variable Frequency Settings & Similar Frequency Range
- Variable Intensity Settings & Similar Output Range
- Biphasic Pulse Waveform
- Similar Pulse Shape & Pulse Charge
- Battery Power & Portability

Using three similar predicate devices, detailed comparisons of specific ES-130 features and characteristics are contained in Section 8 of this submission, in accordance with the FDA publication Guidance Document for Powered Muscle Stimulator 510(k)s. This side-by-side comparison demonstrates that the performance characteristics of the predicate devices encompass the entire range of performance characteristics of the proposed ES-130 device including frequency values, output intensity values, number of channels, supply voltage value, pulse width value, pulse charge value, delivered current density, and delivered power density.

Indication for Use:

The indication for use of ES-130 is an ELECTRO-ACUPUNCTURE DEVICE for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Cited Standards to Determine Substantial Equivalence:

ES-130 complies with FDA recognized standards IEC 60601-1, IEC 60601-1-1, and IEC 60601-2-10. In addition, ES-130 complies with technical requirements outlined in 21 CFR 898.

Non-clinical Testing:

Non-clinical verification and validation resting was conducted on ES-130 device, and the results of such testing appear in Section 18 of this submission. Clinical testing was neither required nor conducted regarding the ES-130 submission. Form FDA-3674 is contained in Section 20 of this submission, which certifies compliance to FDA requirements regarding clinical data.

Truthful and Accuracy Statement:

Signed by a corporate management representative of the submitter, the required statement attesting to the truthfulness and accuracy of the information contained in Section 6 of this submission.

Further Information:

Please contact the following individual to request any further information regarding this submission:

Kenneth L. Block, RAC
Official Correspondent (ITO CO., LTD.)
Ken Block Consulting
1201 Richardson Dr.
Suite 140
Richardson, TX 75080
TEL: 972-480-9554
FAX: 972-767-4325
EMAIL: ken@kenblockconsulting.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ito Co., Ltd.
% Ken Block Consulting
Mr. Kenneth L. Block, RAC
Certified Regulatory Consultant
1201 Richardson Dr., Suite 140
Richardson, Texas 75080

NOV 2 4 2008

Re: K081943
Trade/Device Name: Model ES-130 Electro-Acupuncture Device
Regulation Name: Electro-Acupuncture Stimulator
Regulatory Class: Unclassified
Product Code: BWK
Dated: November 14, 2008
Received: November 17, 2008

Dear Mr. Block:

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 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 Biometrics' (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 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

Indication for Use

510(k) number (if known): K _____

Device name: ES-130

Indication for Use:

The intended use of the ES-130 is an ELECTRO-ACUPUNCTURE DEVICE for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

FOR M. MELKERSON

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

510(k) Number K081943