

## 510(k) SUMMARY

510(k): K091933,

submitters Information: Inno-Health Technology, Co., Ltd.  
8F-2, No.61, Kung Yi Road, Sec. 2,  
Taichung, Taiwan 408, Republic of China

APR - 2 2010

Contact Person: Terry C. Chiang  
Tel: +886- 4 2327 0788

Date Summary Prepared: June 20, 2009

### Device Information:

Classification name: Electro-Acupuncture.  
Common / Usual name: ACULIFE/Model IDOC-01.  
Classification: Class II.  
Regulatory Class: Unclassified.  
Product Code: BWK.

Substantial equivalence: Inno-Health Aculife Electro-Acupuncture/ model SMW-01 (510K number: K051197)

### Description of the Device:

The device consists of a battery powered portable instrument, with a basic power pack which is connected by conducting lead wire to two electrodes (one probe electrode and one big adhesive electrode) which make contact for hands stimulation.

### Indications For Use:

The intended use of ACULIFE/Model IDOC-01 is an ELECTRO-ACUPUNCTURE DEVICE for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

ACULIFE/model IDOC-01 is intended for the stimulation at hands of patient.

### Technological Characteristics:

ACULIFE uses a 4.5V/DC battery or 5V adaptor as the supply power of the stimulation unit. It can be adjusted for the output amplitude, keep the memory of chosen amplitude, and set the operation time. The electrode combination and lead wire provide the electro-acupuncture stimulation for hand by or on the order of a qualified practitioner of acupuncture as determined by the states.

**Performance Data:**

- EN 60601-1 & EN 60601-1-1 for Electric Safety.
- EN 60601-1-2 for EMC.
- ISO 10993 for biocompatibility.
- Output Characteristics testing for product specification.

**Statement of indication for use :** See the following page.

**Conclusion :** Based on the documents provided in the 510(K) submission, the Inno-Health electrod-acupuncture, model ACULIFE/ IDOC-01 is substantial equivalent the chosen FDA cleared model : Inno-Health Aculife Electro-Acupuncture/ model SMW-01 (510K number: K051197).



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Inno-Health Technology, Co., Ltd.  
c/o Mr. Terry C. Chiang  
Official Correspondent  
8F-2, No. 61, Kung Yi Road, Sec. 2  
Taichung, Taiwan 408

APR - 2 2010

Re: K091933  
Trade/Device Name: ACULIFE Model IDOC-01  
Regulatory Class: Unclassified  
Product Code: BWK  
Dated: March 5, 2010  
Received: March 8, 2010

Dear Mr. Chiang:

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.

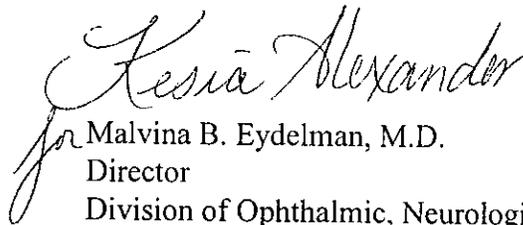
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21 CFR 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,

A handwritten signature in cursive script that reads "Malvina B. Eydelman". The signature is written in black ink and is positioned above the printed name and title.

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

510(k) Number (if known):

Device Name: Electro-Acupuncture; ACULIFE/Model IDOC-01.

### Indications For Use:

The intended use of ACULIFE/Model IDOC-01 is an ELECTRO-ACUPUNCTURE DEVICE for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

ACULIFE/model IDOC-01 is intended for the stimulation at hands of patient.

Prescription Use  OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use   
(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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