K122410

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information:	Medirune Co., Ltd. 3-206,207 Medical Device Industrial Complex, Taejang-dong, Wonju-si, Gangwon-do, Korea (220-120)
Contact Person:	Ho-Kyun Sin
Date Summary Prepared:	Apr 25, 2013

Device description

Trade Name(s):	I Rune (I-200L)
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Panel:	neurology
Product Code & Regulation:	NUH / 882.5890

Predicate Device Information
K102598 / Hi-Dow Model JQ-5C

NOV 1 2 2013

Device Description:
I-RUNE (I-200 L) is a portable pain reliever offering TENS.
The channel **that** effectively transfers your desired choice of programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle contractions. There are **7**modes of operation.

Intended Use:
I-RUNE (I-200 L) is to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Comparison of Output Specification

Comparison	New device (I-200L)	K102598 (JQ-5C)
Max Voltage over 10k, V	71	84
Max Current over 10k, mA	7.1	8.4
Max Voltage over 2k, V	59	85
Max Current over 2k, mA	29.5	42.5
Max Voltage over 500, V	45	62.4
Max Current over 500, mA	90	124.8
Pulse Width, μ seconds	10~160	100
Pulse Period, msec	8.4~187	16.3~781
Max Pulse Frequency, Hz	110	61.3
Max Charge per Phase over 500Ω, μC	9.49	17.92
Max Current Density over 500Ω , mA/㎠	0.15	9.92
Max Average Power Density over 500Ω , mW㎠	0.51	2.72

Summary of non-clinical testing:
Compliance to EN 60601-1, and EN 60601-1 -2 requirement.
In addition to the compliance of voluntary standards, the software verification has been conducted according to the FDA software guidance

Conclusion
Based on the information provided in this summary we conclude that this device is substantially equivalent to the predicate device K102598

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 12, 2013

Medirune Co. Ltd
c/o Yang, Ho Dong
Onbix Corporation
821 Samil Plaza
837-26 Yeuksam-Dong
Gangnam-Gu, Seoul, 135-768
Republic of Korea

Re: K122410
Trade/Device Name: I-Rune (I-200L)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain
Regulatory Class: Class II
Product Code: NUH
Dated: October 30, 2013
Received: November 6, 2013

Dear Yang, Ho Dong:

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 contact 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. 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122410

Device Name: I-RUNE (I-200 L)

Indications For Use:

I-RUNE (I-200 L) is to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/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 Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S