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: Miga Medical Co., Ltd
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Date Summary Prepared: Dec 09, 2013

Device Name:

Trade Name(s):	TG-BODY, MI&Body, S-Trainer
Classification Name:	Powered Muscle Stimulator
Panel:	Physical Medicine
Product Code:	NGX

Predicate Device Information:
K011880 Compex sport stimulator, Compex

Device Description:
The MIGA Co.,Ltd OTC EMS System , model TG-Body, S-Trainer and Mi&Body are intended for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance; it is not intended as a therapy for any medical condition.
Basically the model TG-body, powered by 4.8V, S-Trainer, powered by 3.6V and Mi&Body, powered by 3.7V are muscle stimulation devices and identical to the predicate device - K011880 (Compex Sport) with the following features:

[1] It is a portable, battery operated neuromuscular electronic stimulation system.
[2] It contains 6 programs as similar to the predicate device; the output waveform is selectable pre-programming change among P1-P6 (in case of TG-body 10)
[3] The output strength is adjustable at 0-100mA via regulated voltage, with variable set time 5-60 minutes counting from starting session.
[4] The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low indication.

Intended Use:
TG-BODY, MI&Body, S-Trainer are intended to stimulate healthy muscles in order to improve or facilitate muscle performance and not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

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

*indications for use
*technological characteristics

*performance properties

Comparison table is provided as below.

Features	New Device	New Device	New Device	Predicate Device
510(K) Number	-	-	-	K011880
Device Name, Model	**TG Body**	**Mi&Body**	**S-Trainer**	**Compex sport stimulatior**
Manufacturer	Miga	Miga	Miga	Compex
Power Source(s)	4.8	3.7	3.6	7.2
- Method of Line Current Isolation:	Transformers isolation	Transformers isolation	Transformers isolation	Transformers isolation
- Patient Leakage Current:	-	-	-	-
- Normal Condition	2uA	2uA	2uA	2uA
- Single Fault Condition	13uA	13uA	13uA	15uA
Number of Output Mode	1	1	1	1
Number of Output Channels	4	2	1	4
- Synchronous or Alternating	Synchronous	Synchronous	Synchronous	Synchronous
- Method of Channel Isolation	galvanic	galvanic	galvanic	-
Regulated Current or Regulated Voltage?	500ohm RMS 26mA / RMS 13.0V 2Kohm RMS 8.4mA / RMS 16.8V	500ohm RMS 15mA / RMS 7.5V 2Kohm RMS 4.0mA / RMS 8.1V	500ohm RMS 15mA / RMS 7.5V 2Kohm RMS 4.0mA / RMS 8.1V	500ohm RMS 21mA / RMS 11.8V 2Kohm RMS 7mA / RMS 16V
Software/Firmware/Microprocessor Control	Yes	Yes	Yes	Yes
Automatic Overload Trip	Yes	Yes	Yes	Yes
Automatic No-Load Trip	Yes	Yes	Yes	Yes
Automatic Shut Off	Yes	Yes	Yes	Yes
Patient Override Control	Yes	Yes	Yes	Yes
Indicator Display				
- On/Off Status	Yes	Yes	Yes	Yes
- Low Battery signal	Yes	Yes	Yes	Yes
- Voltage/Current Level	No	No	No	No
Timer Range(Minutes)	1 ~ 60	20 ~33	20 ~ 33	1 ~ 60

Compliance With Voluntary Standards	60601-1.60601-1-1 60601-1-2.60601-2-10	60601-1.60601-1-1 60601-1-2.60601-2-10	60601-1.60601-1-1 60601-1-2.60601-2-10	60601-1.60601-1-1 60601-1-2.60601-2-10
Compliance with 21 CFR898? (Becomes Mandatory Beginning May9,2000)	Yes	Yes	Yes	-
Weight	360g	120g	70g	350g
Dimensions(W*H*D)	106*162*38.5(mm)	64.8*103.6*26(mm)	51*51*14(mm)	142*99*36(mm)
Housing Materials and Construction	ABS	ABS	ABS	Plastic case
the name of the output Mode	Square wave	Square wave	Square wave	Square wave
cleary labeled amplitude and times axes	0~300	0~300	0~300	0~300
identification of the amplitude baseline	-	-	-	-
a list of all output parameter setting	-	-	-	-
the load resistance(in ohms)	-	-	-	-
Waveform(e.g., pulse monophasic,biphasic)	Symmetrical biphasic square	Symmetrical biphasic square	Symmetrical biphasic square	Symmetrical biphasic square
Shape(e.g., rectangular,spike,rectified sinusoidal)	Rectangular	Rectangular	Rectangular	Rectangular
Maximum output Voltage(specify units)	100V peak	40V peak	40V peak	100V peak
Maximum output Current(specify units)	26mA	14.4mA	13.3mA	21mA
Pulse Width(specify units)	50 ~300	150~300	150~300	200 ~ 400
Frequency(Hz)	4 ~100	4~100	4~100	1 ~ 120
Beat Frequency(Hz)	-	-	-	-
For multiphasic waveforms only	-	-	-	-
Symmetrical phases	Yes	Yes	Yes	Yes
Phase duration(include units)(state range, if applicable)(both phases, if asymmetrical)	1 ~ 0.005	0.25 ~ 0.01	0.25 ~ 0.01	0.1 ~ 0.001
net charge(m C per pulse)(if zero, state method of achieving zero net charge)	0	0	0	0

Maximum Phase charge Density(uC)	36	24	24	18
Maximum Current Density(mA/cm2)	1.0432	0. 20571	0. 26473	9.6
Maximum Power Density(W/cm2)(using smallest electrode conductive surface area)	0.06259	0.01059	0.00823	0.046
Burst mode(i.e., Pulse trains)	-	-	-	-
a. pulses per burst	-	-	-	-
b. bursts per second	-	-	-	-
c. burst duration(seconds)	-	-	-	-
d. duty Cycle (line A * line B)	-	-	-	-
ON time(seconds)	10	10	10	-
OFF time(seconds)	10	10	10	-
Additional Features(if applicable)	-	-	-	-

Performance Test Data and Conclusions:
These devices meet consensus standards EN 60601-1, EN 60601-2-10, EN 60601-1-2. Bench testing was also conducted to demonstrate performance specifications.
Based on the information provided in this premarket notification Miga Medical Co., Ltd concludes that the TG-BODY, MI&Body, S-Trainer are safe and effective and substantially equivalent to predicate device as described herein.

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

December 10, 2013

Miga Medical Co., Ltd
c/o Yang Ho Dong
Onbix Corporation
821 Samil Plaza, 837-26 Yeuksam-dong
Gangnam-gu, 135-768 Seoul
South Korea

Re: K122393
Trade/Device Name: TG-Body, MI&Body, and S-Trainer
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: November 20, 2013
Received: November 27, 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. However, we remind you 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,

Victor Krauthamer -A

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): K122393

Device Name: TG-BODY, MI&Body, S-Trainer

Indications For Use:

TG-BODY, MI&Body, S-Trainer are intended to stimulate healthy muscles in order to improve or facilitate muscle performance and not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(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 Center for Devices and Radiological Health (CDRH)

Victor Krauthamer -A
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