K131291

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JUN 14 2013

Summary
Special 510(K)

Submitter's Name	: *JOHARI DIGITAL HEALTHCARE LTD.*
Contact Person	: Ms Pooja Johari
Email	: pooja.johari@7ellc.com
Phone	: 858-657-9226
Fax	: 858-220-7523
Date of Summary Submission	: April 26P, 2013
Resubmitting on	: Not Applicable

Pooja

Name of Person and Signature
(Ms Pooja Johari – Vice President Marketing)

G582-584, EPIP, Boranada, Jodhpur – 342008, Tel: +91-02931-281531/36
info@joharidigita.com

Modified Device for Which Submitting

Device Trade Name	: TORC BODY
Classification Name	: Powered Muscle Stimulator,
	Stimulator, Muscle, Powered, For Muscle Conditioning
Device's Classification Panel	: Physical Medicine
Product Code	: NGX
Regulation	: 890.5850
Address and Registration	: JOHARI DIGITAL HEALTHCARE LTD.
	Electronic Hardware Technology Park
	G-582, 584 E.P.I.P., Boranada,
	Jodhpur 342008
FDA Registration	: 8040537
510(K) No	: Not Known

Legally Marketed Predicate Device

Device Trade Name	: POWERTONE, MODEL PT-11
Classification Name	: Powered Muscle Stimulator
510(K) No	: **K062439**
Address and Registration	: JOHARI DIGITAL HEALTHCARE LTD.
FDA Registration	: 8040537

Description of the Modified Device:

The device description of the *TORC BODY* - Powered Muscle Stimulator is as follows.

TORC BODY is a powered muscle stimulator with two outputs. This battery powered unit is designed for men & women to provide exercise technology. The stimulation is the most comfortable & this technology makes it easier to combine active & passive exercise.

The TORC BODY stimulator provides selections of different programs for Bottom /Thighs muscles (BTS), Abdominal muscles (ABS) & yet customization of stimulation parameters. Four body areas can be treated simultaneously.

The electrical muscle stimulator contracts muscles rhythmically to achieve muscle tone and strength. The belts provided with the device are used to place the electrodes in place on the body area to be treated. The lead wires connect the electrodes with the main stimulator unit. The Torc Body muscle stimulator provides comforting and soothing muscle stimulation to achieve the intended use of strengthening, toning and firming of the muscles of abdomen, thighs and buttocks. The user can increase the intensity to get a stronger stimulation and achieve better results.

A touch screen LCD user interface simplifies the selection of the programs and displays the selected program, treatment time and other stimulation parameters.

Rechargeable batteries power it. The unit can perform anytime & anywhere. Torc Body is suitable for use by all healthy adults. However as with other form of exercise some care is needed when using them.

Torc Body comes complete with all the necessary component to perform Muscle stimulation below is a list of items that are included:

Item	Quantity
1. Torc Body unit	01
2. Electrode cables (3 pole)	02
3. Elastic belt short style	01
4. ABS Belt	01
4. Battery Charger	01
5. Rechargeable Battery pack (Ni-MH)	01

6. Instruction Manual 01

7. Carry bag 01

8. Electrodes – Large (50 mm) 02

Small (40 mm X 80 mm) 04

Technical Specifications Comparison:

Feature	Modified Device: TORC PLUS	Predicate Device: POWERTONE, MODEL PT-11 *(K062439)*
Outputs	Two	Two
Waveform	Symmetrical Biphasic Square Wave	Symmetrical Biphasic Square Wave
Maximum Output Current	102mApp (18.97 mA rms) @500Ω	102mApp (18.97 mA rms) @500Ω
Max output voltage	51 Vpp (9.48 Vrms) @ 500 Ω	51 Vpp (9.48 Vrms) @ 500 Ω
Power Density on Electrodes	0.0089 W/cm2 @500Ω	0.0089 W/cm2 @500Ω
Maximum Phase Charge	35.7μC@500Ω	35.7μC@500Ω
Maximum Current Density	0.176 mA/ cm2	0.176 mA/ cm2
Maximum Power Density	0.0089 W/cm2	0.0089 W/cm2

SUBSTANTIAL EQUIVALENCE:

Feature	Modified Device: TORC BODY	Predicate Device: POWERTONE, MODEL PT-11 *(K062439)*
Indication for Use	TORC BODY is indicated to be used for: - - Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. - Strengthening, Toning and Firming of buttocks & thighs.	POWERTONE is indicated to be used for: - - Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. - Strengthening, Toning and Firming of buttocks & thighs.
Identification	A powered muscle stimulator with two different outputs, which contracts the muscles of specific body areas.	A powered muscle stimulator with two different outputs, which contracts the muscles of specific body areas.
Target of populaces	Healthy adult men & women for home use.	Healthy adult men & women for home use.
Design	1. Torc Body is a micro –computer controlled unit which works on fully charged battery at 24 VDC. The unit generates output (as per features) by digitally controlled micro controller. 2. Microcontrollers activate signal as per selected value and generates the output. 3. The printed circuit board is designed as per the connection of component in electronic schematic diagram	1. Powertone is a micro – computer controlled unit which works on fully charged battery at 4.8 VDC. The unit generates output (as per features) by digitally controlled micro controller. 2. Microcontrollers activate signal as per selected value and generates the output. 3. The printed circuit board is designed as per the connection of component in electronic schematic diagram
Mechanical Size	8.0"(L) x 6.0"(W) x 4.0"(H) It is ABS body enclosure – ergonomically designed, so the unit can be held in hand comfortably or placed on a table while selecting the parameter.	3.9"(L) x 1.6"(H) x 4.0(W) It is ABS body enclosure – ergonomically designed, so the unit can be held in hand comfortably or placed on a table while selecting the parameter

Waveform	The unit Produces different current waveforms. which gives the Muscles stimulation of selectable program Waveform is symmetrical biphasic square wave.	The unit Produces different current waveforms. which gives the Muscles stimulation of selectable program Waveform is symmetrical biphasic square wave.
User Interface & Display	Touch Screen LCD User Interface. LCD displays program mode, percentage power intensity. The remaining time is displayed continuously.	MKB Panel and LCD Display User Interface. LCD displays program mode, percentage power intensity. The remaining time is displayed continuously.
Power	Torc Body is powered by battery pack 24 VDC (consisting of 20 cells of NiMH 1.2 VDC, connected in series). This can be charged by a charger, when device is not in use there by making the use SAFE for the patient	Power tone is powered by four rechargeable NiMH 1.2 VDC size batteries. This can be charged by a charger, when device is not in use there by making the use SAFE for the patient
Humidity	In order to with stand humid atmosphere, insulated liquid are sprayed on circuitry and transformer	In order to with stand humid atmosphere, insulated liquid are sprayed on circuitry and transformer
Storage	32 F to112F	32 F to112F

The modifications made to the device include:

- Name of the device from Powertone to Torc Body
- User Interface to incorporate a touch screen LCD
- High capacity battery from the original device to support the LCD & back light.
- Modified enclosure / plastic case to support touch screen and battery.

The intended use and indications of the modified device are the same as the intended uses and indications for the unmodified predicate device.

The modifications have not altered the fundamental technology of the sponsor's predicate device.

Indications for use:

TORC BODY is indicated to be used for: -

- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.
- Strengthening, Toning and Firming of buttocks & thighs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 14, 2013

Johari Digital HealthCare Ltd.
c/o Ms. Pooja Johari
Vice President, Marketing
5703 Oberlin Dr.
Suite 306
San Diego, CA 92121

Re: K131291
Trade/Device Name: Torc Body
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: April 26, 2013
Received: May 15, 2013

Dear Ms. Johari:

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" (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,

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

Indications for Use

510(k) Number (if known): K131291

Device Name: TORC BODY

Indications For Use:

TORC BODY is indicated to be used for:

- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.
- Strengthening, Toning and Firming of buttocks & thighs.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(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 CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _K131291_____