K110057

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510(k) Summary

Submitter's References
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1. Submitted Device

Trade Name	Mini
Common Name	Sport Muscle Stimulator
Classification Name	Power Muscle Stimulator

1.1. Predicate/Legally Marketed Device

Model	Manufacturer	K Number	Submitted Device
SLENDERTONE ENERVIVE, MODEL 561	BIO-MEDICAL RESEARCH CORP.	K071666	Mini , Model EC12_01
TOP-RANK ADHESIVE ELECTRODE	TOP-RANK HEALTH CARE EQUIPMENT CO., LTD.	K070612	Accessory Electrodes to Mini

1.2. Proposed Indications

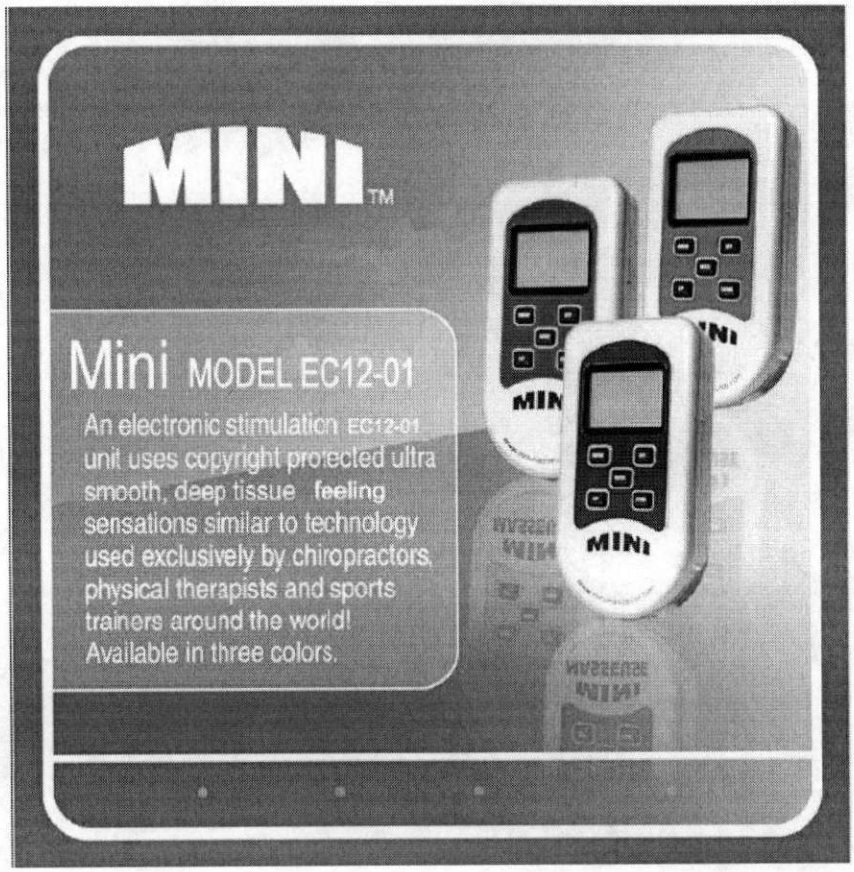
The proposed indications for the predicate Slendertone 561 and the submitted Mini EC12-01 are the same. The design, stimulation energy, stimulation times, stimulation frequency and intended use are exactly the same.

Mini is intended for used by healthy persons to apply transcutaneous electrical muscle stimulation(EMS) through skin contact electrodes. Indications for use are as follows:

Mini is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. Mini is not intended to as a therapy for any medical condition. Please read the indications, precautions and warnings carefully to determine whether any of them apply to you.

Mini stimulates action potentials in the motor nerves supplying muscle. Different patterns of muscle activity can be imposed on the target muscle, depending on the timing and intensity of the stimulation signal. Mini contains programs for exercise warm-up, muscle performance improvement and exercise recovery.

2. Device Description



2.1 Description :

The Mini is a powered muscle stimulator for muscle conditioning. It is a device used for other than medical purposes to apply an electrical current to electrodes on a person's skin to temporarily affect the stimulated muscle's contractile properties, force output, and/or fatigue resistance. Unlike the classified powered muscle stimulator devices intended for use in physical medicine and rehabilitation, this device is not intended for use in patients with medical conditions and is intended only for muscle conditioning purposes.

The Mini is a 9 volt battery powered hand-held device, with detachable electrodes. The electrodes are placed over the muscles which are to be stimulated. The muscles are excited by electric pulses which are created by an electronic circuit. This circuit is software driven, to the user can adjust the stimulation. Mini is pre-programmed with 6 stimulation programs. Programs duration varies depending on the selected mode, which can be reduced by user inputs.

2.2 Structure

- The case of the device is made of ABS plastic. Unit dimensions are 120mm x 60mm x 32mm (L x W x H).
- There is an LCD display on the face for user information.
- Five keys on the face of the device permit user inputs.
- Two electrode inputs are located on the device. Electrodes and leads are supplied as accessories to the device.

2.3 Electronics and Software

Electronics

The functions of the Mini are driven by a CMOS chip, which has a Flash ROM to accommodate the programming. The chip is programmed to deliver pulses to the electronic circuit, corresponding to the 6 stimulation programs. User interface inputs are input into the chip via the interface buttons on the face of the device. The user can manipulate the program, intensity and time duration of the stimulation. Digital signals are sent to the chip and the program responds to the variable inputs. The output of the stimulator is limited by programming and the electronic circuit design. The device is not capable of delivering harmful levels of energy.

Software

Programming for the device is done in Assembly language on the CMOS chip. The program was tested and validated for proper operation.

3. Statement of Intended Use

Mini , Model EC12-01 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

Mini Model EC12-01 is not intended to be used as a therapy for any medical condition. None of the Mini Masseuse programs are designed for injured or ailing muscles and their use on such muscles is contraindicated.

Mini, Model EC12-01 is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation(EMS) through skin contact electrodes. Indications for use are as follows:

Mini is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. Mini is not intended to as a therapy for any medical condition. Please read the indications, precautions and warnings carefully to determine whether any of them apply to you.

Mini stimulates action potentials in the motor nerves supplying muscle. Different patterns of muscle activity can be imposed on the target muscle, depending on the timing and intensity of the stimulation signal. Mini contains programs for exercise warm-up, muscle performance improvement and exercise recovery.

3.1 Training Programs

PROGRAM AND OBJECTIVE
EC12-01 has two programs for muscle performance improvement, as well as programs for exercise preparation and post-exercise active recovery. Depending on your objective your objective, you may select the appropriate program as follows:

Objective	Program number	Intensity Range	Duration
Exercise Preparation	Mode 1	1-10	12
Active Recovery 1	Mode 2	1-10	30
Active Recovery 2	Mode 3	1-10	20
Active Recovery 3	Mode 4	1-10	20
Build Endurance	Mode 5	1-10	20
Build Strength	Mode 6	1-10	20

Mode 1: Build Endurance (20 Min.)
This program gently warms up the muscles prior to exercise. It uses a technique called ""twitch potentiation" to prepare muscle fibers for exercise. It feels like a rhythmic massage. Increase the intensity unit you get a strong, but comfortable muscle movement.

Mode 5: Build Endurance (20 Min.)
This program uses a low frequency pulse train which favors twitch fibers. It develops their aerobic capacity and capillary supply and thereby exercises. The exercise comprises an alternating sequence of work and rest and deep muscle contraction. Do not exceed your comfort level.

Mode 6: Muscle Strengthening(20 Min.)
This program uses a pulse frequency appropriate to fast twitch muscle fibers It develops their aerobic capacity and is used for improving maximum muscle strength. The exercise comprises a sequence of work phases separated by longer relaxation phases. Increase the stimulation intensity until you get a strong and deep contraction. Do not exceed your comfort level.

Mode 2: Active Recovery 1 (30 Min.)
This program produces muscle twitches at very low frequency and it feels like a tapping massage. This stimulates blood flow and helps speed up the removal of lactic acid as it accelerates the exchange between the blood supply and the muscle fibers. As a result, the muscles recover more quickly from fatigue, becoming more relaxed with reduced stiffness. Use it after intense exercise to promote recovery and relaxation.

Mode 3: Active Recovery 2 (20Min.)
This 20-minute program is similar to Active Recovery 1 except that the muscle twitch rate slows down during the session. It feels like a tapping massage, but softer than Active Recovery 1.

Mode 4: Active Recovery 3 (20 Min.)
This from of stimulation activates the muscle in a rhythmic motion in a short contraction/relaxation cycle. It feels like a kneading massage and is smoother than the other active recovery programs.

4. Substantial Equivalence

The submitted Mini EC12-01 is constructed to perform like the predicate Slendertone 561. Both devices have six modes of operation and deliver the same electrical stimulation. The electrical stimulation delivered is alike in pulse frequency, voltage amplitude, pulse width, ramp-up/ramp-down, contraction time, relaxation time, times of stimulation and both have the same claimed effects from the stimulation.

Items	EC12-01	MODEL561 (K071666)	Discussion
Mode/Function	6	6	Same. Basing on the above comparison and detailed description, the subject device's 6 mode is totally same as the predict device's mode Program1-6;
Duration	12-30Mins	12-30Mins	Same.
Intensity Range	1-10 (No sub-level)	1-99 (subdivided into 10 for each 1~10, so total 1~99)	Similar but all matching standards. According to the IEC60601-2-10, each stepped voltage and current does not exceed 10%, the highest and lowest values should less than 2%. The EC12-01 classified the intensity 1~10 according to the standards, the predict device is same as the EC12-01, has 1~10 but subdivided each into 10, so total 1~99. According to the standards, the intensity's safety and effectiveness for both devices is same.
Trigger Function	No	Yes	The predicate device has trigger function, when key it without release, into contraction cycle; but release it, into relaxation cycle. The EC12-01 has no this function.
Output Channels	1	2	Although the number is different, but the two channel of predict device are same, all are synchronous, so the output has the same effect.
Intend for Use	EMS	EMS	Same. EMS (electrical muscle stimulation). Intend to stimulate healthy muscles in order to improve or facilitate muscle performance.

Waveform	Biphasic	Biphasic	Same.

Items	EC12-01	MODEL561 (K071666)	Discussion
Shape	Rectangular	Rectangular	Same.
Net Charge per pulse	0mC	0mC	Same.
Positive Pulse Width	200-300us	200-300us	Same.
Negative Pulse Width	200-300us	200-300us	Same.
Interphase interval	100us	100us	Same.
Regulated Current	Yes	Yes	Same.
Microprocessor Control	Yes	Yes	Same.
Automatic Shut Off	Yes	Yes	Same.
Patient Override Control	No	No	Same.
Compliance with 21 CFR 898	Yes	Yes	Same.
Battery	1X9V 6F22	1X9V 6F22	Same.
Electrodes /Pads	60x50mm	85x50mm	Different, but do not exceed safety limit.
Weight (gram)	87gram	90gram	Weight different
Dimensions (in.) [W x H x D]	2.4' x 4.7' x1.3'	2.4'x3.9' x1.2'	Dimensions different.
Housing Materials and Construction	ABS plastic	ABS plastic	Same.
Low power indication when lower than 3.3V	Yes	Yes	Same.
Lock function	Yes	Yes	Same.

Time countdown	Yes	Yes.	Same.

Items	EC12-01	MODEL561 (K071666)	Discussion
Indication of current mode	Yes	Yes	Same.
Indication of Voltage	No	Yes	EC12-01 does not have indication of voltage.
intensity bar	Yes	Yes	Same.
pad contact indicator	Yes	Yes	Same.
pause	Yes	Yes	Same.

Differences

As noted in the table above, the EC12-01 has ten (10) levels of intensity, and the predicate has 99 levels. Both devices deliver from 0- 40V and 0-80mA. The predicate has control that is more precise in the range of control, but both deliver the same energy for stimulation. This does not constitute a safety or effectiveness difference.

The Slendertone 561 has 2 output channels, while the submitted Mini EC12-01 has a single channel of output. This difference does not constitute a difference in safety or effectiveness. This simply means the predicate device can deliver stimulation to two areas at a time, while the submitted device can deliver stimulation to one at a time.

5. Performance and Safety Testing

Mechanical, environmental safety and performance testing have been accomplished according to the table below to demonstrate this product is substantially equivalent to the predicate device. The submitted device passed all of these tests.

no.	Serial Number/version	Standard and description
1	IEC 60601-1	Medical electrical equipment - Part 1: General requirements for safety
2	IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	IEC 60601-2-10	Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
4	ISO10993-5	Biological Evaluation Of Medical Devices - Part 5: Tests For Cytotoxicity: In Vitro Methods
5	ISO10993-10	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Delayed-Type Hypersensitivity
6	Guidance Document for Powered Muscle Stimulator 510(k)s	FDA Guidance document for Powered Muscle Stimulators

6 Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification The MJ Specialty Retail. Mini ,Model EC12_01is substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MJ Specialty Retail
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Mr. Charles Mack
77325 Joyce Way
Echo, Oregon 97826

OCT 28 2011

Re: K110057
Trade/Device Name: Mini Model EC12_01
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: October 21, 2011
Received: October 25, 2011

Dear Mr. Mack:

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 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" (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,

Ernil Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Mini, Model EC12-01

Indications For Use:

Mini, Model EC12-01 is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

Mini, Model EC12-01 is not intended to be used as a therapy for any medical condition. None of the Mini programs are designed for injured or ailing muscles and their use on such muscles is contraindicated.

Prescription Use ☐ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ☑ (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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110057