K103738

JUN - 1 2011

510(k) Summary
Electronic Waveform Lab Inc.'s H-Wave® Electrical Stimulator (model H4)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Electronic Waveform Lab, Inc.
5702 Bolsa Ave.
Huntington Beach, CA 92649

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Contact Person: Ryan P. Heaney, President

Date Prepared: March 16, 2011

Name of Device

H-Wave® (model H4)

Common or Usual Name/Classification Name

Powered muscle stimulator
21 C.F.R. § 890.5850 (Product Code IPF)

Predicate Devices

H-Wave®(model P-4), Electronic Waveform Lab, Inc. (K915230)

Device Description

The H-Wave® model H4 is a portable battery operated electrical stimulation device with two channels, two sets of lead wires, three packages of self-adhesive electrodes, and a battery charger. Each channel has a pair of buttons to select the desired frequency and a dial to control the intensity of the signal. The stimulator also is supplied with an output jack for each channel, a charging jack, timer buttons, and an LCD display. The device creates therapeutic muscle contractions at frequencies of 1–70 Hz depending on the physician instructions and patient settings.

Intended Use / Indications for Use

1. Relaxation of muscle spasms;
2. Prevention or retardation of disuse atrophy;
3. Increasing local blood circulation;
4. Muscle re-education;
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion.

Performance Data

The H-Wave conforms to the following recognized consensus standards:

- IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.
- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 subclause 56.3(c).
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (2001).

Verification and validation testing of the modifications to the device, including failure analysis of both hardware and software were conducted to ensure that the changes did not affect the safety or effectiveness of the device. In addition, software verification & validation testing was also conducted.

Substantial Equivalence

A detailed chart comparing the H-Wave H4 with the predicate H-Wave P-4 is included below:

510(k) Number		**(K915230)**
Device Name, Model	**H-Wave® (H4)**	**H-Wave® (P-4)**
Manufacturer	Electronic Waveform Lab, Inc.	Electronic Waveform Lab, Inc.
Power Source	Ni-MH rechargeable battery (7.2 V; 1800 mA/h)	NiCad rechargeable battery (10.8V; 700 mA/h)
Line Current Isolation	Yes (battery operated)	Yes (battery operated)
Patient Leakage Current		
Normal Condition	0	0
Single fault condition	0	0
Average DC current through electrodes when device is on but no pulses are being applied (μA)	0	0
Frequency	1–70 Hz	1–70 Hz
Number of output modes	N/A	N/A

510(k) Number		**(K915230)**
Device Name, Model	**H-Wave® (H4)**	**H-Wave® (P-4)**
Number of output channels	2	2
synchronous or alternating	alternating	alternating
Method of Channel Isolation	galvanic	galvanic
Regulated Current or Regulated Voltage	Regulated Voltage	Regulated Voltage
Software/firmware/microprocessor	Yes	No
Automatic Overload Trip	No	No
Automatic No-Load Trip	Yes	No
Automatic Shut Off?	No	No
Patient Override Control	Yes	Yes
Indicator Display		
• On/Off Status	Yes	Yes
• Low Battery	Yes	Yes
• Voltage/Current Level	Yes	Yes
Timer Range (minutes)	0–60 min.	N/A
Compliance with Voluntary Standards	Yes IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators. IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 subclause 56.3(c) IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for	N/A

510(k) Number		**(K915230)**
Device Name, Model	**H-Wave® (H4)**	**H-Wave® (P-4)**
	Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (2001)	
Compliance with 21 CFR Part 898	Yes	Yes
Weight	1.6 lb	2 lb
Dimensions	7" x 4.5" x 1.5"	6"x2.34"x6"
Housing materials and constructions	ABS plastic housing fastened with screws	ABS plastic housing fastened with screws

The H-Wave® configuration covered by this submission has the same intended uses and output parameters as the original cleared H-Wave. The minor differences in the H-Wave's technological characteristics do not raise any new questions of safety or effectiveness. Thus, the H-Wave model H4 is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Electronic Waveform Lab, Inc.
% Mr. Ryan P. Heaney
President
16168 Beach Boulevard
Suite 232
Huntington Beach, California 92647

JUN - 1 2011

Re: K103738
Trade/Device Name: H – Wave (Model H4) Powered Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: May 6, 2011
Received: May 9, 2011

Dear Mr. Heaney:

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,

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 Statement

510(k) Number (if known):_____

Device Name: H-Wave®

Indications for Use:

The H-Wave® is indicated for the following conditions:

1. Relaxation of muscle spasms;
2. Prevention or retardation of disuse atrophy;
3. Increasing local blood circulation;
4. Muscle re-education;
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 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

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