K102524

NOV - 3 2011

510(k) Summary for Futura Pro (US Specification)

(This summary was revised on 21st October 2011)

Sponsor:

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Device Details:

Proprietary name: Futura Pro (US Specification)
Common/Usual name: Futura Pro
Classification Name: Muscle Stimulator, Ultrasound, and TENS (per 21 CFR 890.5860)
Classification: II
Product Code: IMG
Regulation Number: CFR 890.5860
Panel: Physical Medicine Devices

Predicate Devices:

Manufacturer,	Device,	Approval No.:
Ultratone Scientific Instruments Ltd,	Ultratone 20,	K926410
Hwang Sun Enterprise Co. Ltd,	Ultrasonic Therapy Appliance,	K050410

K102524

Device Description

The Futura Pro (US Specification) is a 10 channel Electronic Muscle Stimulator system with a diathermic ultrasound attachment.

The main muscle stimulation part consists of a main control unit which powers and controls a separate stimulator that repetitively contracts skeletal muscles by applying transcutaneous electrical pulses to areas of the body that require therapy for the indicated conditions. These pulses for muscle stimulation are applied via self adhesive electrodes applied on the skin.

The ultrasound attachment is also powered by the main control unit. The diathermic ultrasound signal is delivered via an acoustic coupling gel. The ultrasound applicator has all the necessary controls (on/off amplitude) in the handset and derives only a time controlled power source from the main control unit.

Set programs, with predetermined parameters, are selectable by the operator. On screen instructions guide the user, displaying numbered programs, indication of intensity levels, adjustments, and treatment use. The output leads have indicator LEDs identifying each output as the electrodes are positioned and the intensity adjusted.

The system is powered either internally from a 12V rechargeable sealed battery within the main control unit or via an external12VDC power supply.

Not part of this submission: Electrodes and Conductive gel. Dr. Wenker shall purchase and distribute the FDA-cleared electrodes and coupling gel, which have been specified by Ultratone Scientific Instruments to ensure proper operation of their equipment. Initially, Ultratone Scientific Instruments has specified electrodes and coupling gel from the respective manufacturers, Axelgaard and Parker. Dr. Wenker shall be purchasing and distributing these two items separately.

The stimulator contains safe-start electronic output interlock circuits to ensure stimulation is not suddenly applied to the patient at turn on. The stimulation outputs can subsequently be adjusted by a master output control.

K102524

MUSCLE STIMULATOR

Intended 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
6. Maintaining or increasing range of motion

These intended uses are similar to the predicate marketed device Ultratone 20 K926410.

ULTRASOUND

Intended Use:

Application of deep heat for:
1. Temporary relief of minor pain
2. Muscle spasm relief
3. Joint contracture relief

Not for treatment of malignancies.
Not for use on the face.
These intended uses are similar to the predicate marketed device HES® Ultrasonic Therapy Appliance K050410.

K102524

Technological Comparison - Summary

Powered Muscle Stimulator Part Comparison with Predicate

	Device of this 510(k)	Predicate Device
510(k) No.	TO BE ASSIGNED	K926410
Device Name	Futura Pro (USA Specification)	Ultratone 20
Indications	• Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion	• Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion
Power Source **Internal:** **External:**	 12V battery. 12V charger / adaptor	 12V battery. 15V Charger / adaptor
Number of Output Modes	Two - Biphasic / Monophasic	Two – Biphasic / Monophasic
Number of Output Channels	10 channels	10 channels
Channel Isolation	All outputs are fed via individual output isolating transformers.	All outputs are fed via individual output isolating transformers.
Software / Firmware / Microprocessor Control	All functions are controllable by the microprocessor. All software is contained inside the unit in flash memory. This is not accessible to the operator.	All functions, except output amplitude, are controlled by the microprocessor. All software is contained inside the unit in EPROM. This is not accessible to the operator.
Design	Console sending control signals to a 10 channel electrical muscle stimulation generator. The signal is applied cutaneously via patient connecting leads and self adhesive stimulation electrodes.	Control console incorporating 10 channel electrical muscle stimulation generator. The signal is applied cutaneously via patient connecting leads and stimulation electrodes held in position with straps.
Maximum RMS O/P Current	16.2 mA_{rms} @ 500Ω	15.5 mA_{rms} @ 500Ω
Minimum electrode size	7.0 cm dia. (38.5 cm^2)	10.1 cm dia. (80.1 cm^2)
Maximum Current Density (RMS)	0.421 mA/cm^2 @ 500Ω	0.194 mA/cm^2 @ 500Ω
Maximum RMS Power Density	3.42 mW/cm^2 @ 500Ω	1.50 mW/cm^2 @ 500Ω

K102524

Ultrasound Part Comparison with Predicate

	Device of this 510(k)	Predicate Device
Device Name	Ultrasound Applicator Model No. UFPUA3	Ultrasonic Therapy Appliance Model No. HS 3008
Manufacturer	Hwang Sun Enterprise Co. Ltd. 70955 No. 8, Keji 1st Rd., Annan District, Tainan, Taiwan	Hwang Sun Enterprise Co. Ltd. 70955 No. 8, Keji 1st Rd., Annan District, Tainan, Taiwan
510(k) No.	TO BE ASSIGNED	K050410
Indications	Application of deep heat for: Temporary relief of minor pain Muscle spasm relief Joint contracture relief Not for treatment of malignancies Not for use on the face.	"generates deep heat within body tissues for the treatment of selected medical conditions such as temporary relief of minor pain, muscle spasms and joint contractures, but not for the treatment of malignancies."
Input Voltage	24VDC	24VDC
Timer auto off	Yes	Yes
Max. treatment time	15 min	15 min
Frequency	1000 KHz ±5%	1000 KHz ±5%
Mode	Pulsed and mode where output is switched on/off at 1 Hz.	Pulsed and mode where output is switched on/off at 1 Hz.
Waveform type	Amplitude modulated	Amplitude modulated
Applicator size	Transducer diameter 46.5mm	Transducer diameter 46.5mm
Effective Radiating Area	15 cm^2 ± 10%	15 cm^2 ± 10%
Temporal Max Power	0.97 W ± 10%	0.97 W ± 10%
Temporal Max Effective Intensity	1.47 W/cm^2 ± 10%	1.47 W/cm^2 ± 10%
Beam nonconformity ratio	6:1	6:1
Design	Hand held device generating ultrasonic frequency (1MHz) via incorporated piezoelectric transducer. Power is supplied externally from the Futura Pro console.	Hand held device generating ultrasonic frequency (1MHz) via incorporated piezoelectric transducer. Power is supplied externally from a separate power adaptor.

K102524

Technological Differences between the Futura Pro (US Specification) and the predicates

The significant differences are:

- The Futura Pro (US Specification) has a system where the electrode connectors can be illuminated by the console, for identification of the electrodes. On a multi-channel powered muscle stimulator this aids channel identification.

- The stimulation pulses are applied using disposable self adhesive electrodes rather than conductive rubber electrodes held in place with elastic straps. The self adhesion helps to prevent inadvertent movement of the electrodes during treatment and is considered to be a benefit. The specified electrodes for the Futura Pro (US Specification) are smaller to allow more precision when applying them. It does make the applied current density greater. This is considered acceptable as the resultant current density is well within accepted levels

- The Futura Pro (US Specification) has a screen capable of displaying graphics. This can immediately present relevant information to assist the user in the operation of the device in text and graphical form. The instructions and set up sequence are shown on the display and this assists the operator to carry out the treatment without making errors. This is considered to be a risk lowering benefit with no adverse effect when considered with the predicate.

- The Futura Pro (US Specification) has a more sophisticated control circuitry and software in the powered muscle stimulator to allow groups of output channels to operate independently of the others. This has the advantage of being able to apply different stimulation waveforms to different treatment points. The overall power applied to the patient is limited in the hardware exactly as it is in the predicate by the saturation of each output transformer.

- The Futura Pro (US Specification) provides the hand held ultrasound diathermy device with power. This is taken from the internal low voltage source within the Futura Pro (US Specification) and there are means to stop the ultrasound operation via the console in addition to the control on the hand set. These are considered to be benefits over and above the predicate.

There are no adverse effects from these differences.

K102524

Non-clinical tests

Comparisons of the outputs for the Futura Pro (US Specification) and the predicates show similar results that are suitable for transcutaneous electrical muscle stimulation and the application of deep heat using ultrasound.

In addition to the validation and verification reports submitted in this premarket notification, independent testing has been carried out to demonstrate the device conforms to the following standards:

- BS EN 60601-1:2006 - Medical electrical equipment. General requirements for basic safety and essential performance.
- BS EN 60601-2-10:2001 - Medical electrical equipment. Particular requirements for the safety of nerve and muscle stimulators
- BS EN 60601-2-5:2001 - Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of ultrasonic physiotherapy equipment
- BS EN 55022:2006+A1:2007 - Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement
- BS EN 61000-4-5:2006 - Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test
- BS EN 61000-4-6:2009 - Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields
- BS EN 61000-4-11:2004 - Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests
- BS EN 60601-1-2:2007 – Immunity standard for medical equipment
- BS EN 61000-4-2:1995 – ESD Requirements
- BS EN 61000-4-3:2006+A1:2008 Radiated susceptibility requirement

The manufacturer, Ultratone Scientific Instruments, adheres to recognized and established industry practice for medical devices and all devices are subject to final performance testing.

Clinical tests

No clinical tests were performed.

K102524

Technological Characteristics and Substantial Equivalence Conclusions

Ultratone Scientific Instruments Ltd believes that, based on verification, validations, and safety and performance testing results, the Futura Pro (US Specification) is substantially equivalent to other legally marketed devices and to the standard procedures cited above without raising new safety and/or effectiveness issues. Moreover, any differences in their technological characteristics that do exist would not have a significant effect on the safety or effectiveness of the 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

NOV - 3 2011

Dr. Olivier Wenker, M.D., M.B.A.
% Mr. Courtland Imel
2300 Valley View Lane, Suite 230
Farmers Branch, Texas 75234

Re: K102524
Trade Name: Futura Pro (US Specification)
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and muscle Stimulator
Regulatory Class: Class II
Product Code: IMG
Dated: October 10, 2011
Received: October 13, 2011

Dear Mr. Imel:

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,

Erin D Keith

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

Enclosure

3. Indications for Use Statement

510(k) Number: K102524

Device Name: Futura Pro (US Specification)

MUSCLE STIMULATOR

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
6. Maintaining or increasing range of motion

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

ULTRASOUND

INDICATIONS FOR USE:

Application of deep heat for:

1. Temporary relief of minor pain
2. Muscle spasm relief
3. Joint contracture relief

Not for treatment of malignancies. Not for use on the face.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use XX
(Part 21 CFR 801 Subpart D)

NOT

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

510(k) Number K102524