K111482 1615

AUG 25 2011

510(k) SUMMARY

SONICATOR® PLUS 920, ME 920

Submitter's Name: Mettler Electronics Corp.
Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221 X331
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Contact: Christina Cayuela
QS/RA Manager

Date Prepared: March 17, 2011

AUG 2 5 2011

Proposed Device Name:

a. TRADE NAME: Sonicator® Plus 920 , Model ME 920
b. CLASSIFICATION NAME: Ultrasound and muscle stimulator (Sec. 890.5860, Product Code IMG)
c. COMMON NAME: Combination Ultrasound and Muscle Stimulator

Predicate Device:

TRADE NAME: Sonicator® Plus 940, Model ME 940
510(k) Number: K071137

Description of Proposed Device:

The Sonicator® Plus 920 , Model ME 920 is a two-channel combination unit for therapeutic ultrasound and muscle stimulation. The microprocessor controlled Sonicator® Plus 920 provides interferential (4-pole), pre-modulated(2-pole interferential), medium frequency (Russian), EMS, High Volt, TENS, microcurrent and direct current (DC) waveforms with enhanced reliability and ease of use. In addition the Sonicator® Plus 920 offers 1 and 3 MHz ultrasound using dual frequency 5.5 cm^2 applicator. An optional 0.9 cm^2 applicator at 1 and 3 MHz is also available.

The two-channel Sonicator® Plus 920 allows the clinician to utilize up to two different waveforms using two channels simultaneously. They can choose between several different amplitude modulation options such as the surge, reciprocation and vector sweep The interferential and pre-modulated modes offer frequency modulation as well as a static frequency option.

The Sonicator Plus provides both a membrane panel and a touch-sensitive screen to allow you to quickly set up treatments. 90 preset treatment setups allow quick set up of a treatment that is already in the memory, plus any of these programs may be customized with the clinician's own treatment protocols.

The Sonicator® Plus 920 can provide electrical stimulation only, ultrasound only and combination therapy with the pre-modulated, TENS, High Voltage, microcurrent and DC waveforms.

INDICATIONS FOR USE STATEMENT
SONICATOR® PLUS 920, ME 920

510(k) Number: k111482

Device Name: Sonicator® Plus 920, Model ME 920

Proposed Device Indications for Use (same as those for predicate device):

Therapeutic Ultrasound

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as;

1. Relief of pain, muscle spasms and joint contractures:
2. Relief of pain, muscle spasms and joint contractures that may be associated with:
   - Adhesive capsulitis
   - Bursitis with slight calcification
   - Myositis
   - Soft tissue injuries
   - Shortened tendons due to past injuries and scar tissues
3. Relief of pain, muscle spasms and joint contractures resulting from:
   - Capsular tightness
   - Capsular tightening

4-Pole Interferential, 2-Pole Interferential, TENS and Microcurrent waveforms

1. Symptomatic relief of chronic intractable pain
2. Post-traumatic pain
3. Post-surgical pain

EMS, TENS, Hi Volt and Russian waveforms

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

DC (Direct Current)

1. Relaxation of muscle spasms

Comparison of Technological Characteristics Between Proposed and Predicate Devices:

Section 2

1.	**510 K #**	**K071137**	**K**
2.	**Device Name**	**Sonicator® Plus 940**	**Sonicator® Plus 920**
3.	**Manufacturer**	**Mettler Electronics**	**Mettler Electronics**
4.	**Power Source**	AC line	AC line
	Line Current Isolation	Reinforced insulation	Reinforced insulation
	Max Leakage Current (µA)		
	Chassis	>50 under SFC	> 50 under SFC
	Electrodes	>50 under SFC	>100 under SFC
5.	**Number Of Output Modes**	8	8
6.	**Channel(s)**	4	2
	Synchronous	1 & 2 or 3 & 4	1 & 2
	Reciprocal	1 & 2 or 3 & 4	1 & 2
	Other	Yes	Yes
7.	**Constant Current**	Yes	Yes
	Constant Voltage	No	No
8.	**Software / Firmware / Microprocessor Control**	Yes	Yes
9.	**Automatic Overload Trip**	Yes	Yes
	Automatic Over Current Trip	Yes	Yes
10.	**Automatic No Load Trip**	Yes	Yes
11.	**Automatic Shut Off**	Yes	Yes
12.	**Patient Override**	No	No
	Control Method	On/Off, Hold or Stop	On/Off, Hold or Stop
13.	**Indicator Display**		
	On / Off Status	Yes	Yes
	Voltage/Current Level	Yes	Yes
	Low Battery Indicator	N/A	N/A
14.	**Timer Display:**	0 – 60 minutes	0 – 60 minutes
15.	**Standards**		
	ISO 14971 : 2000	Yes	Yes

UL 2601-1	Yes	Yes
CSA C22.2 NO 601.1-M90	Yes	Yes
IEC/EN 60601-1	Yes	Yes
IEC/EN 60601-1-2	Yes	Yes
IEC/EN 60601-2-10	Yes	Yes
MDD 93/42/EEC, Annex II	Yes	Yes
16. Compliance with 21 CFR 898	Yes	Yes
17. Weight (lbs.)	11	11
18. Dimensions (in.) H x W x L	4.9 x 13.6 x x 10.5	4.9 x 13.6 x x 10.5
19. Housing Materials & Construction	Metal Casing	Metal Casing

Neuromuscular Stimulation, *Section 3*

510 K #	**K071137**	**K**
Device Name	**Sonicator® Plus 940**	**Sonicator® Plus 920**
Manufacturer	**Mettler Electronics**	**Mettler Electronics**
Waveform		
EMS	Biphasic	Biphasic
TENS	Biphasic	Biphasic
Hi Volt	Pulsed Monophasic and Biphasic	Pulsed Monophasic and Biphasic
Russian	Biphasic	Biphasic
Shape		
EMS	Sinusidal	Sinusidal
TENS	Square	Square
Hi Volt	Twin spike	Twin spike
Russian	Gated Sinusoidal	Gated Sinusoidal
Max Output Voltage (V) ±20%		
500 Ω		
EMS	49	50

TENS	46	50
Hi Volt	146	155
Russian	50	50
2 kΩ		
EMS	115	115
TENS	100	110
Hi Volt	155	170
Russian	110	110
10 kΩ		
EMS	120	120
TENS	105	115
Hi Volt	190	220
Russian	120	120
Max Output Current (mA) ±20%		
500 Ω		
EMS	98	100
TENS	90	100
Hi Volt	292	310
Russian	100	100
2 kΩ		
EMS	57	58
TENS	50	55
Hi Volt	78	85
Russian	55	55
10 kΩ		
EMS	12	12
TENS	10.5	12
Hi Volt	19	22
Russian	12	12
Pulse Width Range		
EMS	500, 250, 200 µs	500, 250, 200 µs
TENS	100 - 600 µs	100 - 600 µs
Hi Volt	10 - 80 µs	10 - 80 µs
Russian	400 µs	400 µs
Frequency (Hz)		
EMS	2 kHz, 4 kHz, 5 kHz	2 kHz, 4 kHz, 5 kHz

TENS	0.5 - 250 Hz	0.5 - 250 Hz
Hi Volt	0.5 - 200 Hz	0.5 - 200 Hz
Russian	2.5 kHz	2.5 kHz
Beat Frequency (Hz)		
Interferential, 2-pole, *Premodulated*	1 - 250 Hz	1 - 250 Hz
Multiphasic Waveforms.....		
Symmetrical Phases?		
EMS	Yes	Yes
TENS	Yes	Yes
Hi Volt	Yes	Yes
Russian	Yes	Yes
Phase Duration		
EMS	250, 125, 100 µs	250, 125, 100 µs
TENS	50 - 300 µs	50 - 300 µs
Hi Volt	10 - 80 µs	10 - 80 µs
Russian	200 µs	200 µs
Net Charge	Zero	Zero
Symmetry	Symmetric	Symmetric
Method	Balanced	Balanced
Maximum Phase Charge (µC)		
500 Ω		
EMS	12.7	15.9
TENS	60	60
Hi Volt	48	48
Russian	12.7	15.9
Maximum Current Density		
(mA/cm², 500 Ω)		
EMS	2.96*	2.46
TENS	1.91*	1.97
Hi Volt	1.87*	2.32
Russian	3.50*	3.45
Maximum Power Density		
(W/cm², 500 Ω)		
EMS	0.089	0.062
TENS	0.037	0.039

Hi Volt	0.035	0.054
Russian	0.121	0.121
Burst Mode		
a. Pulses per burst		
EMS	N/A	N/A
TENS	7	7
Hi Volt	7	7
Russian	N/A	N/A
b. Bursts per second		
EMS	N/A	N/A
TENS	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7
Hi Volt	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7
Russian	0 – 100	0 – 100
c. Burst duration (ms)		
EMS	N/A	N/A
TENS	70	70
Hi Volt	120	120
Russian	2, 4, 6.....20	2, 4, 6.....20
d. Duty Cycle (b x c)		
EMS	N/A	N/A
TENS	3.6 - 77.8 %	3.6 - 77.8 %
Hi Volt	6.3 % to 85.7 %	6.3 % to 85.7 %
Russian	10, 20, 30, ...100%	10, 20, 30, ...100%
On Time (ms)		
EMS	1 - 99	1 - 99
TENS	1 - 30	1 - 30
Hi Volt	1 - 30	1 - 30
Russian	1 - 30	1 - 30
Off Time (s)		
EMS	1 - 99	1 - 99
TENS	1 - 99	1 - 99
Hi Volt	1 - 99	1 - 99
Russian	1 - 99	1 - 99

Pain Management, *Section 3*

510 K #	K071137	K
Device Name	**Sonicator® Plus 940**	**Sonicator® Plus 920**
Manufacturer	**Mettler Electronics**	**Mettler Electronics**
Waveform		
Interferential, 4-pole	Biphasic	Biphasic
Interferential, 2-pole, *Premodulated*	Biphasic	Biphasic
TENS	Biphasic	Biphasic
Microcurrent	Biphasic and pulsed monophasic	Biphasic and pulsed monophasic
Shape		
Interferential, 4-pole	Sinusidal	Sinusidal
Interferential, 2-pole, *Premodulated*	Sinusidal	Sinusidal
TENS	Square	Square
Microcurrent	Square	Square
Max Output Voltage (V) ±20%		
500 Ω		
Interferential, 4-pole	48	50
Interferential, 2-pole, *Premodulated*	49	50
TENS	46	50
Microcurrent	0.38	0.37
2 kΩ		
Interferential, 4-pole	110	115
Interferential, 2-pole, *Premodulated*	115	110
TENS	100	115
Microcurrent	1.55	1.5
10 kΩ		
Interferential, 4-pole	120	120
Interferential, 2-pole, *Premodulated*	120	115
TENS	105	125
Microcurrent	7.5	7.4
Max Output Current (mA) ±20%		
500 Ω		

Interferential, 4-pole	96	100
Interferential, 2-pole, *Premodulated*	98	100
TENS	90	100
Microcurrent	0.760	0.74
2 kΩ		
Interferential, 4-pole	55	58
Interferential, 2-pole, *Premodulated*	57	55
TENS	50	58
Microcurrent	0.780	0.75
10 kΩ		
Interferential, 4-pole	12	12
Interferential, 2-pole, *Premodulated*	12	12
TENS	10.5	13
Microcurrent	0.750	0.74
Pulse Width Range		
Interferential, 4-pole	500, 250, 200 µs	500, 250, 200 µs
Interferential, 2-pole, *Premodulated*	500, 250, 200 µs	500, 250, 200 µs
TENS	100 - 600 µs	100 - 600 µs
Microcurrent	1.25 ms - 1.67 s	1.25 ms - 1.67 s
Frequency (Hz)		
Interferential, 4-pole	2 kHz, 4 kHz, 5 kHz	2 kHz, 4 kHz, 5 kHz
Interferential, 2-pole, *Premodulated*	2 kHz, 4 kHz, 5 kHz	2 kHz, 4 kHz, 5 kHz
TENS	0.5 - 250 Hz	0.5 - 250 Hz
Microcurrent	0.3 - 400 Hz	0.3 - 400 Hz
Beat Frequency (Hz)		
Interferential, 4-pole	1 - 250 Hz	1 - 250 Hz
Interferential, 2-pole, *Premodulated*	1 - 250 Hz	1 - 250 Hz
Multiphasic Waveforms.....		
Symmetrical Phases?		
Interferential, 4-pole	Yes	Yes
Interferential, 2-pole,	Yes	Yes

Premodulated		
TENS	Yes	Yes
Microcurrent	Yes	Yes
Phase Duration		
Interferential, 4-pole	250, 125, 100 µs	250, 125, 100 µs
Interferential, 2-pole, *Premodulated*	250, 125, 100 µs	250, 125, 100 µs
TENS	50 - 300 µs	50 - 300 µs
Microcurrent	1.25 ms - 1.67 s	1.25 ms - 1.67 s
Net Charge	Zero	Zero
Symmetry	Symmetric	Symmetric
Method	Balanced	Balanced
Maximum Phase Charge (uC)		
500 Ω		
Interferential, 4-pole	12.7	15.9
Interferential, 2-pole, *Premodulated*	12.7	15.9
TENS	60	60
Microcurrent	75	75
Maximum Current Density		
(mA/cm², 500 Ω)		
Interferential, 4-pole	3.50*	3.45
Interferential, 2-pole, *Premodulated*	2.96*	2.46
TENS	1.91*	1.97
Microcurrent	0.026*	0.026
Maximum Power Density		
(W/cm², 500 Ω)		
Interferential, 4-pole	0.121	0.121
Interferential, 2-pole, *Premodulated*	0.089	0.062
TENS	0.037	0.039
Microcurrent	0.000007	0.000007
Burst Mode		
a. Pulses per burst		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole,	N/A	N/A

Premodulated		
TENS	7	7
Microcurrent	N/A	N/A
b. Bursts per second		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7
Microcurrent	N/A	N/A
c. Burst duration (ms)		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	70	70
Microcurrent	N/A	N/A
d. Duty Cycle (b x c)		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	3.6 - 77.8 %	3.6 - 77.8 %
Microcurrent	N/A	N/A
On Time (s)		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	1 - 30	1 - 30
Microcurrent	N/A	N/A
Off Time (s)		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	1 - 99	1 - 99
Microcurrent	N/A	N/A

Muscle Spasm, *Section 3*

510 K #	K071137	K
Device Name	Sonicator® Plus 940	Sonicator® Plus 920
Manufacturer	Mettler Electronics	Mettler Electronics
Waveform		
Continuous DC	DC	DC
Shape		
Continuous DC	DC	DC
Max Output Voltage (V) ±20%		
500 Ω		
Continuous DC	10.2	10.5
2 kΩ		
Continuous DC	28	26
10 kΩ		
Continuous DC	34	31
Max Output Current (mA) ±20%		
500 Ω		
Continuous DC	20	21
2 kΩ		
Continuous DC	14	13
10 kΩ		
Continuous DC	3.4**	3.1
Maximum Current Density (mA/cm², 500 Ω)		
Continuous DC	0.99	0.99
Maximum Power Density (W/cm², 500 Ω)		
Continuous DC	0.0079	0.0098
On Time (s)		
Continuous DC	Controlled by probe	Controlled by probe
Off Time (s)		
Continuous DC	Controlled by probe	Controlled by probe

Therapeutic Ultrasound

510 K #	K071137	K
Device Name	**Sonicator® Plus 940**	**Sonicator® Plus 920**
Manufacturer	**Mettler Electronics**	**Mettler Electronics**
Power Source	AC Line	AC Line
Standards		
ISO 14971 : 2000	Yes	Yes
UL 2601-1	Yes	Yes
CSA C22.2 NO 601.1-M90	Yes	Yes
IEC/EN 60601-1	Yes	Yes
IEC/EN 60601-1-2	Yes	Yes
IEC/EN 60601-2-5	Yes	Yes
FDA, 21 CFR 1050.10	Yes	Yes
MDD 93/42/EEC, Annex II	Yes	Yes
Timer Accuracy:	± 3 %	± 3 %
Maximum Treatment Time:	30 minutes	30 minutes

Ultrasonic Generator Specifications

Frequency	1 MHz and 3 MHz, ± 5 %	1 MHz and 3 MHz, ± 5 %
Modes	Continuous and Pulsed	Continuous and Pulsed
Pulse Repetition Rate	100 Hz ± 10 %	100 Hz ± 10 %
Pulse Duration	0.5, 1.0, 2.0. 3.0, 4.0 and 5 ms (±10 %)	0.5, 1.0, 2.0. 3.0, 4.0 and 5 ms (±10 %)
Temporal Peak/ average intensity ratio	2:1 ± 20 % at 50 % Duty Cycle 2.5 :1 ± 20 % at 40 % Duty Cycle 3.3:1 ± 20 % at 30 % Duty Cycle 5:1 ± 20 % at 20 % Duty Cycle 10:1 ± 20 % at 10 % Duty Cycle 20:1 ± 20 % at 5 % Duty Cycle	2:1 ± 20 % at 50 % Duty Cycle 2.5 :1 ± 20 % at 40 % Duty Cycle 3.3:1 ± 20 % at 30 % Duty Cycle 5:1 ± 20 % at 20 % Duty Cycle 10:1 ± 20 % at 10 % Duty Cycle 20:1 ± 20 % at 5 % Duty Cycle
Maximum output power	12 W for ME 9401 1.8 W for ME 9402	12 W for ME 9201 1.8 W for ME 9202
Maximum intensity	2 W/cm² for continuous mode 3 W/cm² for pulsed mode	2 W/cm² for continuous mode 3 W/cm² for pulsed mode

Indication accuracy	± 20 %	± 20 %

Ultrasonic Applicator Specifications

Piezoelectric discs	Ultrasound transducer attached to a metal surface and patient contact through the metal	Ultrasound transducer attached to a metal surface and patient contact through the metal
Applicator Part Number	**ME 9401**	**ME 9201**
Frequency	1 MHz and 3 MHz ±5%	1 MHz and 3 MHz ±5%
Effective Radiating Area	5.5 cm^2 (1 MHz) / 6.0 cm^2 (3 MHz)	5.5 cm^2 (1 MHz) / 6.0 cm^2 (3 MHz)
Maximum Beam Non–Uniformity Ratio	4.55 : 1 maximum	4.6:1 (1 MHz) / 4.2:1 (3 MHz) maximum

Applicator Part Number	**ME 9402**	**ME 9202**
Frequency	1 MHz and 3 MHz ±5%	1 MHz and 3 MHz ±5%
Effective Radiating Area	0.9 cm^2 (1MHz) / 0.9 cm^2 (3 MHz)	0.9 cm^2 (1MHz) / 0.8 cm^2 (3 MHz)
Maximum Beam Non–Uniformity Ratio	4.68 : 1 maximum	4.7:1 maximum

Other Applicators	None	None
Frequency	N/A	N/A
Effective Radiating Area	N/A	N/A
Maximum Beam Non–Uniformity Ratio	N/A	N/A

* Values shown are current correct values for ME940 device and reported in mA/cm^2 to match the same mA/cm^2 nomenclature reported for ME920 device (values appearing in original K071137 submission were in A/cm^2)

** Value shown is correct value for ME940 device (value appearing in original K071137 submission was erroneously reported as 17 mA, much higher than the actual correct lower value of 3.4 mA shown above)

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

Mettler Electronics Corporation
% Ms. Christina Cayuela
QS/RA Manager
1333 South Claudina Street
Anaheim, CA 92805

AUG 25 2011

Re: K111482
Trade/Device Name: Sonicator® Plus 920, Model ME 920
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and muscle stimulator
Regulatory Class: II
Product Code: IMG, GZJ, GZI and IPF
Dated: July 20, 2011
Received: July 26, 2011

Dear Ms. Cayuela:

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

510(k) Number (if known): k111482

Device Name: Sonicator® Plus 920, ME 920

Indications for Use:

Therapeutic Ultrasound

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as;

1. Relief of pain, muscle spasms and joint contractures:
2. Relief of pain, muscle spasms and joint contractures that may be associated with:
   - Adhesive capsulitis
   - Bursitis with slight calcification
   - Myositis
   - Soft tissue injuries
   - Shortened tendons due to past injuries and scar tissues
3. Relief of pain, muscle spasms and joint contractures resulting from:
   - Capsular tightness
   - Capsular tightening

4-Pole Interferential, 2-Pole Interferential, TENS and Microcurrent waveforms

1. Symptomatic relief of chronic intractable pain
2. Post-traumatic pain
3. Post-surgical pain

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

510(k) Number K111482

EMS, TENS, Hi Volt and Russian waveforms

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

DC (Direct Current)

Relaxation of muscle spasms

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)