MAR - 2 2001

510 (K):K993229(Revised submission) ANNEXURE 'VII'

SUMMARY

JOHARI ELECTRO TECH CO.
EC-2, Electronics Complex, Light Industrial Area, Jodhpur 342003 (INDIA)
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"510(k) Summary"

Submitter's name	:	JOHARI ELECTRO TECH CO.
Address	:	EC-2, Electronics Complex Light Industrial Area Jodhpur 342003 INDIA
Phone	:	91-291-741183
FAX	:	91-291-742289
E-mail	:	joharis@ndf.vsnl.net.in
Contact Person	:	Mrs. Nisha JOHARI
Date of Summary is submitted	:	Resubmitting on August 9th. 2000.

Device for which clearance is required

Trade Name	:	Analgesic Pulser AP-439
Common Name	:	Electrical Nerve Muscle Stimulator
Classification Name	:	Physical Medicine (Per 21 CFR Section 890) and Neurology (Per 21 CFR Section 882.5890).

Legally Marketed Device I

(a) Sys stim 226 (b) Sys stim 206	:	Muscle Stimulator 510(k) Number K964028
Manufacturer	:	Mettler Electronics Corp.
Address	:	1333 S. Claudia St. Anaheim Ca. 92805
Tel.	:	001 (714) 533 2221

AP-439 has same intended use as predicate. Both the electrical stimulators are to be used in Physical Medicine by Clinicians and Therapists.

Intended Use of Sys Stim 226 and 206

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain (Interferential or Premodulated Waveforms).
2. Temporary relaxation of muscle spasm.
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles.
4. Increase of blood flow in the treatment area.
5. Prevention or retardation of disuse atrophy in post-injury type conditions.
6. Muscle re-education.
7. Maintaining or increasing range of motion.

Legally Marketed Device II:

Sportx	: Pulsed Direct Current (Muscle) and Nerve Stimulator
Manufacturer	: Staodyn

Address: : 1225 Florida Avenue, Longmont, Colorado 80502-1379, 1-800-343-0488 or 1-800-525-2114

The predicate Device Sportx from Staodyn is indicated for

Pulsed Direct Current (PDC) has been used successfully for many years for the reduction of edema, increase or decrease in blood flow, increase in range of motion and relief of muscle spasm. Transcutaneous Electrical Nerve Stimulation (TENS) has been used successfully for many years in the symptomatic relief and management of chronic, intractable pain or as an adjunctive treatment in the management of chronic, intractable pain or as an adjunctive treatment in the management of acute post-surgical or post-traumatic pain.

AP-439 ------

Indication for Use (A) Interferential current stimulation, Premodulated Bipolar Mode and Faradic Stimulation Mode is indicated for;

1. Symptomatic relief and management of chronic (long term) intractable pain.
2. Adjunctive treatment in the management of post-surgical and post-traumatic, acute pain conditions.

(B) Electrical Muscle Stimulation (Russian and Galvanic-Interrupted) is indicated for:

1. Relaxation of Muscle spasm.
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

(C) Galvanic-DC Continuous mode is indicated for:-

1. Relaxation of muscle spasm.

TECHNICAL SPECIFICATIONS

ANALGESIC PULSER AP-439

Power Source	: 110V AC +/- 50Hz - 60Hz
Number of outputs	: Two
Channels	: Four
Synchronous	: Yes
Max out put current	: Faradic - 100 mA pp at 500 Ohm Load Interferential - 72mA RMS (Root Mean Square) at 500 Ohm Load DC continuous - 30 mA at 500 Ohm Load DC Interrupted - 92 mA at 500 Ohm Load
Max out put voltage	: Faradic – 132 V peak to peak at load of 10K ohms Interferential – 50 V RMS at load of 10K ohms DC continuous – 28 V at load of 10K ohms DC Interrupted - 60 V at load of 10K ohms.
Channel isolation	: Yes, confirm to ANSI 3.2.3.2 , 1985.
Waveform	: Monophasic, Biphasic, Sinewave & D.C. Line
Current density on 2" diameter electrodes	Interferential 3.55mA/Sq. cm on 500 ohm load Galvanic (D.C. continuous) 1.5 mA/Sq. cm on 500 ohm load Galvanic Interrupted 2.1mA/ Sq.cm on 500 Ohm Load Faradic (Narrow Low Freq, Wide Low Freq., Dual, Ramp Burst Paired, Surge) 0.592 mA/Sq. cm on 500 ohm load

Power density on 2" diameter electrodes	Interferential 0.127 W/Sq. cm on 500 ohm load Galvanic (DC Continuos) 0.022 W/Sq. cm on 500 ohm load Galvanic (DC Interrupt) 0.095 W/Sq. cm on 500 ohm load Faradic (Narrow Low Freq, Wide Low Freq., Dual, Ramp Burst Paired, Surge) 0.029 W/Sq. cm on 500 ohm load
Max. phase charge	Interferential (Quadipolar,vector,premod)
at 500 Ohm	4.5 micro coulomb
at 2 K Ohm	1.5micro coulomb
at 10 K Ohm	0.3micro coulomb
	Interferential (Russian)
at 500 Ohm	7.2 micro coulomb
at 2 K Ohm	2.4micro coulomb
at 10 K Ohm	0.5 micro coulomb
	Galvanic (DC interrupted)
at 500 Ohm	40 micro coulomb
at 2 K Ohm	15 micro coulomb
at 10 K Ohm	3.2 micro coulomb
	Faradic (Narrow Low Freq, Wide Low Freq., Dual, Ramp Burst Paired,Surge)
at 500 Ohm	20 micro coulomb
at 2 K Ohm	9.6 micro coulomb
at 10 K Ohm	3 micro coulomb
<u>Modulation Options</u> Amplitude	Preset IFT only
Frequency	IFT section only
Mechanical Specifications	Weight 5.5 Lb, 12.2" (l)X 3.5" (h)X 7.5" (d)
Pulse width	Faradic: 100-400 (selectable) IFT : 125 micro sec. phase interval Russian :200Micro Seconds Galvanic : D.C.

DC interrupted: At values greater than 50%power the on time is 1600 micro secs. And the total time is 3.5 milli secs.At values lower than the 50 % power the on time is 800 micro secs. and total time is 3.5 millisecs.

Sys stim: 226

Waveform:	Sinewave and biphasic rectangular pulse
Volts:	65 V RMS at 1 K load (interferrential mode) , 99 V pp at load of 1K ohms.(biphasic mode) 0-50 V RMS at 1 K ohms load.(Russian ,premodulated mode)
Current:	65 mA RMS at 1 K load (interferrential mode) , 99 mA peak at load of 1K ohms.(biphasic mode).0-50 mA RMS at 1 K ohms load.(Russian ,premodulated mode
Average current at Max. intensity & freq.:	65 mA (interferrential mode) , 7.2 mA(biphasic mode) 50 mA.(Russian ,premodulated mode)
Max. current density : Under 2" diameter Electrode:	3.2 mA/cm2 (interferrential mode) , 0.36 mA/cm2(biphasic mode) 2.5 mA/cm2.(Russian ,premodulated mode
Phase duration:	125 us (interferrential mode) ,50 – 300 us (biphasic mode) 200 mA.(Russian)

Sys Stim 206

Waveform:	Biphasic,monophasic pulse,DC.
Volts:	0 – 102 VDC
Current:	100 mA peak,All pulsed Waveforms. 30 mA max. in Dc continuos.
Average current at: Max. intensity and freq.	------

Max. current density: Under 2" diameter Electrode:	------
Phase duration:	Narrow pulse: 100 us followed by 400 us at ¼ amplitude of reverse polarity. Wide pulse: 300 us followed by 1200 us at ¼ amplitude of reverse polarity. AC: 300 us in each polarity DC: DC Continuos

Sportx

Waveform:	Multiplexed symmetrical rectangular biphasic and unbalanced symmetrical rectangular triphasic.
Volts:	100 V at load of 2 K ohms.
Current :	100 mA at load of 500 ohms.
Average current at: Max. intensity & freq.	------
Max. current density Under 2" diameter Electrode:	------
Phase duration:	Symmetrical biphasic: 1800 us Unbalanced triphasic 1800 us and 900 us

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2001

Ms. Nisha Johari
Director of Marketing
Johari Electro-Tech Company
Vandana, 28 Nehru Park
Jodhpur-342003,
India

Re: K993229
Trade Name: Analgesic Pulser, Model AP-439
Regulatory Class: II
Product Code: GZJ, IPG and LIH
Dated: December 1, 2000
Received: December 5, 2000

Dear Ms. Johari:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K):K993229(Revised submission) ANNEXURE 'VIII'

DEVICE NAME: ANALGESIC PULSER AP-439

INDICATION FOR USE : (A) Interferential current stimulation ,Premodulated Bipolar Mode and Faradic Stimulation Mode is indicated for;

1 Symptomatic relief and management of chronic (long term) intractable pain.
2 Adjunctive treatment in the management of post-surgical and post-traumatic, acute pain conditions.

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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

(C) Galvanic-DC Continuous mode is indicated for:-

1. Relaxation of muscle spasm.

Nisha Jahan

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR
Over-The-Counter-Use _____:

(Per 21CFR 801.109) (Optional Format 1-2-96)

8.1

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K993229