

JUL 13 1998

Nisha Communication Industries

EC-3, Electronics Complex, Light Industrial Area, JODHPUR-342 003 (India)

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12980040

" 510 (k) Summary"

Submitter's name : Nisha Communication Industries

Address : EC 3, Electronic Complex
Light Industrial Area
Jodhpur 342003
India.

Phone : 91 - 291 - 741183

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Contact Person : Mrs. Nisha Johari

Date the Summary
is submitted : January 5th '98.
resubmitting on March 10th '98.

Device for which clearance is required

K980040

Trade Name : Microstim J-1304D
Common Name : Electrical Muscle Stimulator
Classification Name: Physical Medicine (Per 21 CFR Section 890-5850)

Legally Marketed Device

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

Microstim J 1304D has same intended use as predicate. Both the muscle stimulators are to be used in Physical Medicine by Clinicians and Therapists.

SUMMARY:

12980040

Description:- (Principle, Mode & Design)

Microstim J-1304D is an electrotherapy unit used for electrical Muscle Stimulator. This microprocessor based circuit generates biphasic square pulse, with enhanced accuracy and dependability. The pulse duration is preset to most effectively stimulate motor fibers. The waveforms are delivered in an envelope of trapezium shaped impulse. The stimulation is more effective yet being smooth and comfortable.

Such Muscle Stimulation has traditionally been used to prevent disuse atrophy in patients unable to exercise their own muscles because of debilitating or traumatic injury. Muscle Stimulation is also considered appropriate for range of motion exercises, reducing spasm, increasing blood flow, muscle re-education and or to prevent venous thrombosis.

J-1304D provides such treatment to four patients simultaneously. Each channel separately has power increase and start/stop key. The increase in intensity by touch button key on membrane panel gives very smooth rise. It delivers exact amount of current that can be visualized as % power in display window. There are four frequency parameters to choose from 200,300,600 and 800 Hz. The treatment time can be selected from 15,30,45 and 60 min. Cyclic 'off' time at 0 gives advantage of reaching the maximum tolerance level or desired level of intensity and then selection from 2 sec,4 sec, and 8 sec 'off' time for kind of treatment.

The design of Microstim J-1304D, as having slanted front panel, is for the ease of use to the clinician. Made of aluminum it is strong and sturdy.

The unit is supplied with lead wire, four electrode wires and four sets of self adhesive electrodes.

Electrodes are legally marketed in US
mfr. by:- Conmed Corporation
at 310, Broad street,
Utica NY. 13501 U.S.A

Intended Use

Microstim J 1304D is an Electrical Muscle Stimulator to be used by Physiotherapy or clinicians in Physical Medicine for following applications:-

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

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Technical Specification
Microstim J - 1304 D

Power Source	110V AC +/- 10%	50 Hz - 60 Hz
Number of output modes :		
Channels	Four	
Synchronous	Yes	
Max. output current	40 mA Peak at 500 Ohm (+/- 5%)	
Max. output voltage	60 V Peak at 10 Kohm (+/- 5%)	
Channel isolation	Yes (conforms to ANSI NS4 sec. 3.2.3.2. 1985)	
Waveform	Biphasic	
Current Density	1.97mA / Sq. cm (under 2 inches diameter electrodes)	
Power Density	39.47 mW / Sq. cm (under 2 inches diameter electrodes)	
Max. Phase charge		
at 500 ohm	40 mA x 0.6 msec = 24 micro coulomb	
at 2 Kohm	20 mA x 0.6 msec = 12 micro coulomb	
at 10 Kohm	6 mA x 0.6 msec = 3.6 micro coulomb	

Modulation Options

Amplitude	V peak values are :- 20V at 500 ohm 40V at 2 Kohm 60V at 10 Kohm
Frequency	Selected from 200, 300, 600, 800 PPS.
Mechanical Specification	Weight :- 8.8 lb. Size :- 17"(l) X 13"(b) X 6"(w)
Pulse width	0.6 msec.
Amp. Modulation options	2 sec and 4 sec - 8sec off time
Avg. current at max. intensity and frequency on Cyclic off "8 sec."	10 mA
Max. current density under 2" diameter electrodes	1.97 mA/cm ²



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mrs. Nisha Johari
c/o Mrs. Reena Daga
Nisha Communication Industries
Canyon Creek Apartment J-146
10201 Lindley Avenue
Northridge, California 91325

Re: K980040
Electronic Muscle Stimulator - Microstim J-1304D
Regulatory Class: II
Product Code: IPF
Dated: June 25, 1998
Received: June 30, 1998

Dear Mrs. 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.

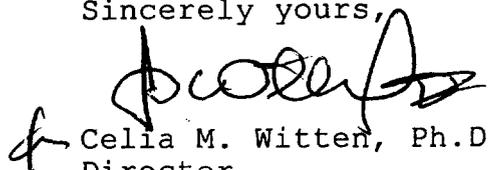
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

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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,


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

Enclosure

510(k) Number (if known): K980040

Device Name: Microstim 1304D

Indications For Use:

- (1) Relaxation of Muscle Spasm.
- (2) Prevention or retardation of disuse atrophy.
- (3) Increasing local blood circulation.
- (4) Muscle re-education.
- (5) Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.
- (6) Maintaining or increasing range of motion.

(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 General Restorative Devices
 510(k) Number K980040

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use