K050046

APR 13 2005

Summary of Safety and Effectiveness:

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Applicant Information

Compex Technologies, Inc.
1811 Old Highway 8
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Contact Person

Brian J. Edwards, M.S.
Director of Regulatory Affairs & Quality Assurance

Date Summary Prepared

September 1, 2004

Device identification

Trade / Proprietary Name:	IF 3Wave Interferential Muscle Stimulator System, Model 7110S
Common / Usual Name:	Muscle and Interferential Current
Classification Name:	21 CFR 890.5850 "Powered Muscle Stimulator"
Product Classification:	Class II
Product Code:	IPF

Legally Market Predicate Devices

The IF 3Wave Interferential Stimulator System, Model 7110S is comparable in type and function and are substantially equivalent to the following predicate devices.

Predicate Device	510(k) Number / Clearance Date
Staodyne, Inc. EMS+2 Neuromuscular Stimulation System	K926510 / August 11, 1993
Medical Devices, Inc. Model IF-II Interferential Stimulation System	K923914 / November 6, 1992
Staodyne, Inc. Model SporTX Pulsed Direct Current and TENS Stimulator	K921668 / August 3, 1992
Axelgaard Manufacturing Company TENS Pals Plus Electrodes	K872976 / September 22, 1987
Axelgaard Manufacturing Company Valutrode Electrodes	K970426 / May 9, 1997

Device Description

The IF 3Wave is a non-invasive medium/low frequency interferential muscle stimulation device intended for treating patients that have acute and chronic pain, edema, tight musculature, muscle spasms and muscular weakness due to disuse atrophy. The IF 3Wave stimulator is a microprocessor controlled dual channel Interferential electro-stimulator with neuro-muscular and pulse direct current stimulation capabilities. It will offer 4 separate electro-therapy stimulation modalities. These modalities are interferential, (IF), neuromuscular electrical stimulation (NMES), pulsed direct current (PDC) electrical stimulation, and a combination of interferential and neuromuscular electrical stimulation (IF/NMES).

The IF 3Wave will be capable of storing device settings, use, and compliance data for up to 90 days. It will be capable of down loading the above compliance date through a phone line modem, which is contained within the battery charger base. Once per month, the patient will be instructed to download the stored data from their device, which will create a patient compliance report which is forwarded to their physicians for review. The physician will review the report and provide adjustment to the patient treatment regimen and device setting accordingly.

Accessories provided with the IF 3Wave include lead wires, electrode pads, rechargeable battery pack, battery charger/modem, phone cable, power supply, and a users manual.

Technical Characteristics

The IF functional mode of the IF 3Wave is substantially equivalent to the functional mode of the Rehabilicare IF-II device.

Interferential Modality.

	IF-II Model 7100S	IF 3Wave Model 7110S
510(k) Number	K923914	
Manufacturer	Medical Devices, Inc.	Compex Technologies, Inc.
Power Source	4 AA rechargeable batteries Line Powered Repack	Lithium ion polymer rechargeable battery.
Weight	12 oz, with battery	12 oz, with battery
Dimensions	3.2 x 5.2 x 1.15 in.	3.89 x 6.33 x 1.42 in
Case Materials	ABS/PC Blend	Same
Patient Leakage Current* Normal Single Fault	 Unknown Unknown	 < 0.1 microamperes 2.4 microamperes
Output Modes	1	3
Number of Output Channels	2	Same
Method of Channel Isolation	Transformer isolation	Same
Regulated Current or Voltage	Voltage	Same
Software, Firmware, Microprocessor Controlled	Yes	Same
Automatic Overload Trip	No	Yes, 5 kohms
Automatic No-Load Trip	Yes	Same
Automatic Shut-off	Yes	Same
Patient Override Controls	Yes	Same
Indicator Display On/Off Status Low Battery Voltage, Current Level	 Yes Yes Yes	 Same Same Same
Waveform	Symmetrical biphasic square wave with 0 net DC	Same
Pulse Width	125 microseconds	Same
Carrier Pulse Frequency (Channel 1)	4000 Hz, fixed	Same
Adjustable Pulse Frequency (Channel 2)	4001 – 4150 Hz	Same
Interferential Beat Frequency	1 – 150 Hz	Same
Pulse Amplitude	0 – 50 mA, adjustable in 1 mA steps into 500 ohm load	Same

Indications for Use	Relieve acute pain Relieve and manage chronic pain Relax muscle spasms Maintain and increase the range of motion Increase local blood circulation	Same
Number of Continuous Treatments	1	Same
Continuous Treatment Time Selection	20 minutes, fixed	10 – 60 minutes, selectable in 5 minute steps
Number of Variable Sweep Programs	3	4
Sweep Treatment Time Selection	20 minutes, fixed	10 – 60 minutes, selectable in 5 minute steps
Sweep Program Cycle Times	1 sec Up / 1 sec Down 6 sec Up / 6 sec Down	6 sec Up / 6 sec Down 12 sec Up / 12 sec Down 24 sec Up / 24 sec Down
Number of Fixed Parameter Sweep Programs	0	7
Sweep Program Frequency Range	1 – 150 Hz, selectable continuously using a rheostat	1 – 150 Hz, selectable in 1 Hz steps
Maximum Charge per Pulse	120 microcoulombs	Same
Maximum Output Voltage	50 volts, peak-to-peak, 500 ohm load	Same
Peak Output Current	100 mA, peak-to-peak, 500 ohm load	Same
Net Charge per Pulse	0 microcoulombs, biphasic waveform	Same
Max Phase Charge	6.25 microcoulombs	Same
Max Current Density#	1.937 mA / cm^2 (average)	Same
Max Power Density#	0.097 W/cm^2 (average)	Same
Burst Modes	N/A	N/A
Compliance with Voluntary Standards	Unknown	Yes, refer to page 43 of the submission for list

*Patient Leakage Current was determined following test procedure within IEC 601-1

#These values were calculated using the average current over time, not pulse current, with a 500 ohm load.

The NMES functional mode of the IF 3Wave is substantially equivalent to the functional mode of the Rehabilicare EMS+2 device.

NMES Modality.

	EMS+2 Model 6840S	**IF 3Wave Model 7110S**
510(k) Number	K926510	
Manufacturer	Staodyne, Inc.	Compex Technologies, Inc.
Power Source	9 volt battery – alkaline or nickel metal hydride rechargeable	Lithium ion polymer rechargeable battery.
Weight	7.97 oz, with battery	12 oz, with battery
Dimensions	5.4 x 3.2 x 1.2 in.	3.89 x 6.33 x 1.42 in
Case Materials	ABS/PC Blend	Same
Waveform	Symmetrical biphasic with zero net DC component	Same
Patient Leakage Current* Normal Single Fault	 Unknown Unknown	 < 0.1 microamperes 2.4 microamperes
Output Modes	1	3
Number of Output Channels	2	Same
Method of Channel Isolation	N/A	Same
Regulated Current or Voltage	Current	Same
Software, Firmware, Microprocessor Controlled	Yes	Same
Automatic Overload Trip	No	Same
Automatic No-Load Trip	Yes	Same
Automatic Shut-off	Yes	Same
Patient Override Controls	Yes	Same
Indicator Display On/Off Status Low Battery Voltage, Current Level	 Yes Yes Yes	 Same Same Same
Number of Preset Programs	0	6
Pulse Width	50 - 300 microseconds, adjustable	70 – 300 microseconds in 10 microsecond steps
Pulse Frequency	4 – 80 Hz, adjustable	10 – 80 Hz in 5 Hz steps
Pulse Amplitude	0 – 100 mA across a 1000 Ohm load, adjustable	0 – 100 mA in 1 mA steps across a 1000 Ohm load
Indications for Use	Relax muscle spasms Prevent or retard disuse atrophy Increase local blood circulation Re-educate muscles Maintain or increase the range of motion	Same

	Prevent venous thrombosis using immediate postsurgical stimulation on calf muscles	
Treatment Time Selection	15, 30, or 60 minutes, or Continuous, selectable	10 – 60 minutes, in 5 minute increments
Cycle ON Time	0.5 - 30 seconds, adjustable	1 – 30 seconds, in 1 second increments
Cycle OFF Time	0.1 - 60 seconds, adjustable	1 – 60 seconds, in 1 second increments
Ramp-Up Time	0.1 - 6, adjustble	0 -10 seconds, in 1 second increments
Ramp-Down Time	0.1 – 6 seconds, adjustable	0 – 10 seconds, in 0.5 second increments
Maximum Output Voltage	100 volts, 0-to-peak, 1000 ohm load	Same
Peak Output Current	100 mA, 0 -to-peak, 1000 ohm load	Same
Maximum Charge per Pulse	30 microcoulombs	Same
Net Charge per Pulse	0 microcoulombs, biphasic waveform	Same
Max Phase Charge	30 microcoulombs	Same
Max Current Density#	0.19 mA/cm^2 (average)	Same
Max Power Density#	0.019 W/cm^2 (average)	Same
Burst Modes	N/A	N/A
Compliance with Voluntary Standards	Unknown	Yes, refer to page 43 of the submission for list

*Patient Leakage Current was determined following test procedure within IEC 601-1

#These values were calculated using the average current over time, not pulse current., with a 500 ohm load.

The PDC functional mode of the IF 3Wave is substantially equivalent to the functional mode of the Rehabilicare SporTX device.

PDC Modality.

	SporTX Model 7700S	**IF 3Wave Model 7110S**
510(k) Number	K921668	
Manufacturer	Staodyne, Inc.	Compex Technologies, Inc.
Power Source	9 volt alkaline or rechargeable battery	Lithium ion polymer rechargeable battery.
Weight	4.4 oz, with battery	12 oz, with battery
Dimensions	2.1 x 4.2 x 0.9 in	3.89 x 6.33 x 1.42 in
Case Materials	ABS/PC Blend	Same
Patient Leakage Current* Normal Single Fault	 Unknown Unknown	 < 0.1 microamperes 2.4 microamperes
Output Modes	1	3
Number of Output Channels	2	Same
Method of Channel Isolation	N/A	Same
Regulated Current or Voltage	Current	Same
Software, Firmware, Microprocessor Controlled	Yes	Same
Automatic Overload Trip	No	Same
Automatic No-Load Trip	Yes	Same
Automatic Shut-off	Yes	Same
Patient Override Controls	Yes	Same
Indicator Display On/Off Status Low Battery Voltage, Current Level	 Yes Yes Yes	 Same Same Same
Waveform 1	Symmetrical biphasic squarewave with zero net DC	Same
Waveform 2	Unbalanced Triphasic with positive net DC	Same
Number of Preset Programs	0	3
Pulse Width	Biphasic: 60 microseconds Triphasic: 60 microseconds	Same
Pulse Frequency	Biphasic: 278 Hz Triphasic: 222 Hz	Same
Pulse Amplitude	0 – 100 mA across a 1000 Ohm Load, adjustable	0 – 100 mA in 1 mA increments across a 1000 Ohm load
Indications for Use	Reduction of edema (under negative electrode)	Same

	Reduction of muscle spasm Influencing local blood circulation Retardation or prevention of disuse atrophy Facilitation of voluntary motor function Maintenance or increase of range of motion	
Treatment Time Selection	38 minutes or Continuous, selectable	30 – 60 minutes, in 5 minute increments
Maximum Output Voltage	100 Volts, 100 ohm load	Same
Maximum Charge per Pulse	6 microcoulombs	Same
Average DC Current	266 microamperes	300 microamperes
Net Charge per Pulse	0 microcoulombs, biphasic waveform	Same
Max Phase Charge	60 microcoulombs per pulse	Same
Max Current Density#	0.13 mA/cm^2 (average)	Same
Max Power Density#	0.013 W/cm^2 (average)	Same
Burst Modes	N/A	N/A
Compliance with Voluntary Standards	Unknown	Yes, refer to page 43 of the submission for list

*Patient Leakage Current was determined following test procedure within IEC 601-1

#These values were calculated using the average current over time, not pulse current., with a 500 ohm load.

Indications for use

The IF 3Wave Interferential Stimulator System is intended for:

Interferential stimulation can be used for the following applications:

- Relieve acute pain
- Relieve and manage chronic pain
- Relax muscle spasms
- Maintain and increase the range of motion
- Increase local blood circulation

Neuromuscular stimulation can be used for the following applications:

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Increase local blood circulation
- Re-educate muscles
- Maintain or increase the range of motion
- Prevent venous thrombosis using immediate postsurgical stimulation on calf muscles

Pulsed direct current stimulation can be used for the following applications:

- Reduction of edema (under negative electrode)
- Reduction of muscle spasm
- Influencing local blood circulation (under negative electrode)
- Retardation or prevention of disuse atrophy
- Facilitation of voluntary motor function
- Maintenance or increase of range of motion

Interferential and Neuromuscular combination stimulation can be used for the following applications:

- Reduction of edema (under negative electrode)
- Reduction of muscle spasm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2005

Compex Technologies, Inc.
c/o Mr. Daniel Lehtonen
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K050046
Trade/Device Name: IF 3 Wave Interferential Muscle Stimulator System, Model 7110S
Regulation Numbers: 21 CFR 890.5850, 21 CFR 882.5890
Regulation Name: Powered muscle stimulator, Transcutaneous electrical nerve stimulator for pain relief and Interferential current therapy
Regulatory Class: II
Product Codes: GZJ, IPF and LIH
Dated: March 28, 2005
Received: March 29, 2005

Dear Mr. Lehtonen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K050046

Device Name

Compex Technologies IF 3Wave Interferential Stimulator System, Model 7110S.

Indications for Use

Interferential stimulation can be used for the following applications:

- Relieve acute pain
- Relieve and manage chronic pain
- Relax muscle spasms
- Maintain and increase the range of motion
- Increase local blood circulation

Neuromuscular stimulation can be used for the following applications:

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Increase local blood circulation
- Re-educate muscles
- Maintain or increase the range of motion
- Prevent venous thrombosis using immediate postsurgical stimulation on calf muscles

Pulsed direct current stimulation can be used for the following applications:

- Reduction of edema (under negative electrode)
- Reduction of muscle spasm
- Influencing local blood circulation (under negative electrode)
- Retardation or prevention of disuse atrophy
- Facilitation of voluntary motor function
- Maintenance or increase of range of motion

Prescription Use _X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Restorative

Devices

K050046