NOV 1 0 2011 K111557

Traditional 510(k) **ANNEXURE 'IV'**

SUMMARY

"Traditional 510(k) summary"

SUBMITTER'S NAME	:	Seven Seas Distribution and Manufacturing LLC
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Date of summary submission : 25th April 2011
Resubmitting on : 12th October 2011

For Seven Seas Distribution and Manufacturing LLC
Mark Ioele

NEW DEVICE FOR WHICH SUBMITTING

Trade Name : **X-Force**

Common Name : **TENS (Transcutaneous Electrical Nerve Stimulator)**

Classification Name : **Transcutaneous electrical nerve stimulator for pain relief (21 CFR 882.5890, Product Code NYN)**

Device's Classification Panel : **Neurology**

LEGALLY MARKETING DEVICE

J-Stim 1000 : Transcutaneous Electrical Nerve Stimulator

Manufacturer : **Pain Management Technologies, Inc.**

Address : **1340 Home Ave. , Bldg A, Akron, OH 44310**

DESCRIPTION OF NEW DEVICE X-Force

The **X-FORCE** device is a microcomputer controlled digital device featuring a NT Mode output. The device provides simple programming facility to customize the treatment. The panel and its keys provide easy selection for treatment. It is device that deploys the use of electrotherapy and compression to treat Osteoarthritis (OA) and rheumatoid arthritis of the knee or hand.

The X-Force consists of electrodes, the lead wires, and the signal generator. The device is portable and rechargeable battery operated. The lead wires connect the electrodes to the device. These electrodes complete an electrical circuit allowing current to flow. The stimulator produces a pulsed electrical signal through the lead wires and electrodes at the treatment site.

Device Features:

- Digital LCD display
- Dual channel
- Soft fabric comfortable garment
- Low battery indicator
- ABS Portable handy device
- Parameter locking

ACCESSORIES:

X-Force comes complete with all the necessary accessories and below is a list of items that are included:

Units are supplied with:

- Electrode Cable (2 Pin 2 Core); Length: 1.25 meter conforming to 21 CFR 898
- Knee Belt listed in the 510(k) – K073386 of Jstim 1000
- Elbow Belt and Conductive Patches listed in 510(k) – K943009
- Conductive Gel
- Battery Rechargeable AA size 1.2 V (4 in qty.)
- External Battery Charging Adaptor

  Adaptor Specifications
  - INPUT: 100-240V AC-50/60Hz
  - OUTPUT: 5.5V DC
- Instruction Manual

INTENDED USE OF NEW DEVICE "X-FORCE"

The X-Force external, non-invasive, non-narcotic, electrotherapy system is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee.

The X-Force is also indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the Hand.

INTENDED USE OF PREDICATE DEVICE "J-STIM 1000"

The J-Stim 1000 external, non-invasive, non-narcotic, electrotherapy system is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee.

The J-Stim 1000 is also indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the Hand.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

S. No	Description	New Device X-Force	Predicate Device JSTIM (K073386)	Remarks
1	Energy Source	Rechargeable battery (4 X 1.2V)operated, more battery backup compare to Predicate device	9V Alakaline battery operated	Similar
2	Device Housing	Material - ABS Size – (142 X 62 X 26) mm 12.875 ounce (365 Grams) with battery, 8.924 ounce (253 Grams) without battery	Material - ABS Size – (45 x 30 x 15) mm 2.8 ounce (65 Grams) with battery, 1.6 ounce (45.8 Grams) without battery	Similar
3	Number of Output Channels	Two Channels	Two Channels	Same
4	Number of Modes	One	One	Same
6	Display	Customized LCD	Customized LCD	Similar
7	Waveform	NT (HiVolt) – Pulsed Monophasic	NT (HiVolt) – Pulsed Monophasic	Same
7	Treatment Timer	YES	YES	Same
8	Target of populaces	Therapist in Neurology at health clinic and Chiropractor.	Therapist in Neurology at health clinic and Chiropractor.	Same

COMPARISON OF BASIC UNIT CHARACTERISTICS:

S.N	FEATURES OF DEVICE	NEW DEVICE	PREDICATE DEVICE
1	510(K) Number	K111557	K073386
2	Device Name, Model	X Force	JStim 1000
3	Manufacturer	Seven Seas Distribution and Manufacturing LLC	Pain Management Technologies, Inc.
4	Power source	Rechargeable Battery(4 X 1.2V - AA size)	9V Li ion battery
5	Method of Line Current Isolation	(a) Since Instruments operates on battery, hence it is completely isolated from Mains Supply.	(a) Since Instruments operates on battery, hence it is completely isolated from Mains Supply.
6	Patient Leakage Current Normal condition Single Fault condition	(b) Patient Leakage Current Normal condition = less than 100µA* Single fault condition = less than 300µA* * Reference:IEC 60601-1	(b) Patient Leakage Current Normal condition = less than 100µA* Single fault condition = less than 300µA* * Reference:IEC 60601-1
7	Number of Output Modes	1	1
8	Number of Output Channels Synchronous or Alternating?	Synchronous Channel 1 and 2 are completely isolated. Both have designated Amplifier & control circuit, Only power supply and ground are common.	Synchronous Channel 1 and 2 are completely isolated. Both have designated Amplifier & control circuit Only power supply and ground are common
9	Regulated Current or Regulated Voltage	Regulated Voltage	Regulated Voltage
10	Maximum Output Current	Iavg =0.2mA @ 500Ω	Iavg =0.2mA @ 500Ω
11	Maximum Output Voltage	Vavg. =0.108Vavg @ 500Ω	Vavg. =0.108Vavg @ 500Ω
12	Maximum Phase Charge	24.3 µC @ 500Ω	24.3 µC @ 500Ω
13	Maximum Current Density	0.0021 mA/cm^2 @ 500Ω	0.0021 mA/cm^2 @ 500Ω
14	Maximum Power Density	0.00022 mW/cm^2 @ 500Ω	0.00022 mW/cm^2 @ 500Ω
15	Software/Firmware/ Microprocessors Controls?	YES	YES
16	Automatic Overload Trip?	YES	YES
17	Automatic No-Load Trip	YES	YES
18	Automatic Shut off?	YES	YES
19	Patient Override Control?	YES	YES
20	Indicator Display: On/Off Status? Low Battery? Voltage/Current Level?	 YES YES YES	 YES YES YES
21	Timer	YES	YES
22	Compliance with Voluntary Standards	NO	NO
23	Compliance With 21 CFR 898	YES, the electrode cable can never be plugged in the AC	YES, the electrode cable can never be plugged in the AC

24	Weight	socket, not even accidentally 12.875 ounce (365 Grams) with battery, 8.924 ounce (253 Grams) without battery	socket, not even accidentally 2.8 ounce (65 Grams) with battery, 1.6 ounce (45.8 Grams) without battery
25	Dimension (L X B X H)	(142 X 62 X 26) mm	(45 x 30 x 15) mm
26	Housing Material	ABS resine	ABS resine

SUMMARY:

XForce functions in the same way as the predicate device Jstim 1000. The intended use, operational characteristics of both the devices are similar.

Indication Comparison: Indented use of X Force and Predicate Device are same i.e. X Force is indicated for use as an adjective Therapy in reducing the level of pain and symptoms associated with Osteoarthritis of the knee and Rheumatoid Arthritis of the Hand.

Technological Comparison: The technological characteristics (Energy Source, Design, Material and Physical Characteristics) of modified device has been compared with Jstim 1000 and found to be same as the predicate device Jstim 1000.
Below are the differences:

1) **Power source:** Jstim 1000 has power source of 9Volt where as X-Force have Power source of 1.2 DC X 4 Battery) which are more power full compare to 9VDC battery thus giving more battery backup. This change only increase battery backup of Unit and there is no effect on the safety or effectiveness of the device.

2) **Program Lock feature:** X-Force have Program Lock feature which is not present in Jstim 1000. This feature give user to lock the used parameter, this function doesn't affect any parameter which can make New device different from Predicate

3) **Digital Control of Output Power**: Jstim 1000 output power is controlled through Analog pots where in X-Force Output power is controlled digitally through Microcontroller.

Labeling Comparison : Labeling of the device compares to that of predicate device.

Non-Clinical Testing : Not Applicable as Jstim 1000 is already FDA Approved and the New Device X-Force is same as Predicate Device

Clinical Testing : Not Applicable as Jstim 1000 is already FDA Approved and the New Device X-Force is same as Predicate Device

Conclusion : Drawn from the comparison between the modified device X-Force with predicate device J Stim 1000, it demonstrates that X-Force is as safe, as effective and performs as well as its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Seven Seas Distribution and Manufacturing, LLC
c/o Mr. Mark Ioele
President
2620 S. Maryland Pkwy, Ste. 14 Unit 835
Las Vegas, Nevada 89109

NOV 10 2011

Re: K111557
Trade/Device Name: X Force
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NYN
Dated: October 12, 2011
Received: October 27, 2011

Dear Mr. Ioele:

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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SEVEN SEAS DISTRIBUTION
AND MANUFACTURING LLC

INDICATIONS FOR USE

510(K) No : K111557

Device Name : X Force

Indications For Use:

The **X-Force** external, non-invasive, non-narcotic, electrotherapy system is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee.

The **X-Force** is also indicated for use as an adjunctive therapy in reducing the level of pain, and stiffness associated with pain, from rheumatoid arthritis of the Hand.

These devices are to be used or sold only under the direct supervision or order of a licensed practitioner. A prescription is required to obtain this product. The product can be used in the home or clinic by all patients in need.

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

(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 Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111557

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