K060246

Johari Digital Healthcare Ltd.

REGD. OFFICE :
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ISO 9001 Certified

MAY - 5 2006

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

SUMMARY

"Traditional 510(k) Summary"

Submitter's name	:	**JOHARI DIGITAL HEALTHCARE LTD.**
Address	:	**EC-1-2-3, Electronics Complex** **Light Industrial Area** **Jodhpur - 342003 INDIA**
TELEPHONE	:	+91-2931-281535, 281536
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Contact Person	:	**Pooja Johari**
Date of Summary is submitted	:	**January 18, 2006**
~~Resubmitting on~~	:	_____

Nisha Johari

NEW DEVICE FOR WHICH SUBMITTING

Trade Name : **INFREX**

Common Name : **Interferential & Transcutaneous Electrical Nerve Stimulator**

Classification Name : **Neurology (Per 21 CFR Section 882-5890).**

Distributed by : **MedFaxx, Inc.**
P. O. Box 1289
Wake Forest, N. C. 27588
tel: 800-937-3993 tel2:919-570-0350
fax: 919-570-0354
bobjohnson@medfaxxinc.com
http://www.medfaxxinc.com

LEGALLY MARKETED DEVICE

TENS TS1211 : **Transcutaneous Electrical Nerve Stimulator**
510(k) Number K021755

Manufacturer : Apex Medical Corp., Taiwan
Address : P.O.Box, 18-17
Taipei, Taiwan

IF-4000 : **Interferential Stimulator**
510(k) Number K952683

Manufacturer : Apex Medical Corp., Taiwan
Address : P.O.Box, 18-17
Taipei, Taiwan

DEVICE DESCRIPTION

INFREX is a Microcomputer controlled portable two channel electrical stimulator. It allows the treatment specifically tailored to the precise needs of the patient.

The unique feature of this unit is that it is supplied with two removable packs of rechargeable batteries and an external charger. The user can put one battery pack in the unit for treatment and another spare pack can be charged outside the unit using the supplied external charger. This system facilitates the user to have charged batteries always available and the treatment can be taken any time. Often the units available in the market consume lot of power and batteries die fast.

The Rubber Key Pad operation and LCD protocols makes the use and programming easy and simple. All the parameters remain in the system control except the amplitude & time selectable, which can be set by the patient himself. The ergonomic design makes this unit very comfortable to worn and carry.

INFREX comes complete with all the necessary components to perform Pain Management Stimulation. Below is a list of items that are included:

		Quantity
1.	**INFREX** unit	01
2.	Electrode Cable (2 pole, length-1.15m)	02
3.	Electrode (Self Adhesive, size -2" round)	04
4.	Rechargeable batteries AAA (Ni-Mh)	02 packs, (4 in each pack)
5.	External Charger	01
6.	Carry Bag	01
7.	Manual	01

Indications for Use

510(k) Number (if known): - K060246

Device Name: INFREX
INFREX is indicated to be used for: -

- Symptomatic relief and management of chronic intractable pain.
- Adjunctive treatment in the management of post surgical and post–traumatic, Acute pain condition.

TECHNICAL SPECIFICATIONS OF NEW DEVICE INFREX

Power Source:	1.2 Volts * 4Ni – Mh battery pack.
Number of outputs:	Two
Channels	Two
Synchronous	Yes
Max Output Current: (Peak to Peak)	**TENS** 60 mA @ 500 Ohms. 24mA @ 2K Ohm. 5.4mA @10K Ohm. **IFT** 54 mA @ 500 Ohms.. 21mA @ 2K Ohm. 4.4mA @10K Ohm.
Max Output Voltage: (Peak to Peak)	**TENS** 30 V @ 500 Ohms. 48V @ 2K Ohm. 54V @10K Ohm. **IFT** 27V @ 500 Ohms Load. 42V @ 2K Ohm. 44V @10K Ohm.
Channel isolation	Yes, confirm to ANSI 3.2.3.2 , 1985
Waveform	Symmetrical Biphasic Square Wave
Pulse width	**TENS** 50, 100, 150, 200 and 250 µS selectable. **IFT** 125 µS.
Frequency	**TENS** 5 and 60 Hz selectable **IFT** Channel 1: 4000 Hz. Channel 2: 4080 to 4150 Hz.

Max. Phase charge	**TNS** 7.500 µc @ 500 Ohms Load. 3.000 µc @ 2K Ohms Load. 0.675 µc @ 10K Ohms Load. **IFT** 3.375 µc @ 500 Ohms Load. 1.312 µc @ 2K Ohms Load. 0.275 µc @ 10K Ohms Load.
Current Density on 2" Electrodes:	**TENS** 0.089 mA / cm^2 @ 500 Ohms Load. 0.0355 mA / cm^2 @ 2K Ohms Load. 0.008 mA / cm^2 @ 10K Ohms Load. **IFT** 2.66 mA / cm^2 @ 500 Ohms Load. 1.036 mA / cm^2 @ 2K Ohms Load. 0.217 mA / cm^2 @ 10K Ohms Load.
Power Density on 2" Electrodes:	**TENS** 0.0027 Watt / cm^2 @ 500 Ohms Load. 0.0017 Watt / cm^2 @ 2K Ohms Load. 0.0004 Watt / cm^2 @ 10K Ohms Load. **IFT** 0.0718 Watt / cm^2 @ 500 Ohms Load. 0.0435 Watt / cm^2 @ 2K Ohms Load. 0.0095 Watt / cm^2 @ 10K Ohms Load.
Modulation Options: Amplitude Frequency	Applicable only in IFT Mode.
Mechanical Specifications	5.12" x 2.76" x 1.1" (L x B x H)

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

TECHNICAL SPECIFICATIONS OF PREDICATE DEVICE TENS TS 1211

Power Source:	+9 Volts Alkaline Battery or Ac Adaptor
Number of outputs:	Two
Channels	Two
Synchronous	Yes
Max Output Current: (Peak to Peak)	80 mA @ 500 Ohms Load
Max Output Voltage: (Peak to Peak)	40 V @ 500 Ohms Load.
Channel isolation	Yes, confirm to ANSI 3.2.3.2, 1985.
Waveform	Asymmetrical Biphasic Square Wave
Pulse width	50 to 300 µS.
Frequency	2 to 150 Hz.
Max. Phase charge	24.000 µc @ 500 Ohms Load.
Current Density on 2" Electrodes:	0.355 mA / cm^2 @ 500 Ohms Load.
Power Density on 2" Electrodes:	0.0142 Watt / cm^2 @ 500 Ohms Load.
Modulation Options: Amplitude Frequency	Not Applicable
Mechanical Specifications	3.9" x 2.75" x 1" (L x B x H)

TECHNICAL SPECIFICATIONS OF PREDICATE DEVICE IF-4000

Power Source:	+9 Volts Alkaline Battery or Ac Adaptor
Number of outputs:	Two
Channels	Two
Synchronous	Yes
Max Output Current: (Peak to Peak)	32 mA @ 500 Ohms Load
Max Output Voltage: (Peak to Peak)	16 V @ 500 Ohms Load.
Channel isolation	Yes, confirm to ANSI 3.2.3.2, 1985.
Waveform	Symmetrical Biphasic/Square Wave
Pulse width	125 μS.
Frequency	Channel 1: 4000 Hz Channel 2: Channel 1 + (-55% of Sweep Frequency to +25% of Sweep Frequency). Sweep Frequency is selectable thru rotary Knob in between 1 to 150 Hz.
Max. Phase charge	4.00 μc @ 500 Ohms Load.
Current Density on 2" Electrodes:	1.578 mA / cm^2 @ 500 Ohms Load.
Power Density on 2" Electrodes:	0.02525 Watt / cm^2 @ 500 Ohms Load.
Modulation Options: Amplitude Frequency	Amplitude Modulation thru Slide Switch..
Mechanical Specifications	3.74" x 2.52" x 0.95 (L x B x H)

TECHNOLOGICAL CHARACTERISTICS

1. **MICRO-CONTROLLER**
INFREX uses a high-speed microcontroller for all data generation. This makes data or parameters accurate or precise and they do not change over time. In predicate devices, TENS 1211 also uses a micro controller, but IF 4000 is an analog devices and the precision of data is not as much as in **INFREX.**

2. **MULTICHANNEL**
INFREX & TENS TS1211 & IF-4000 have two channels to provide Interferential stimulation to treat one body area. Similarly in INFREX and both predicate devices have two channels to provide TENS stimulation to treat two body areas.

3. **MULTIWAVE SELECTIONS & PROGRAMABILITY**
INFREX produces selection of Interferential Stimulation (frequency of **4000** Hz and one fixed beat frequency 80Hz to 150 Hz. Sweep) and TENS of two selectable frequency – 5Hz and 60Hz (Default 60Hz) waveforms for pain relief through both the outputs.
Predicate device IF-4000 provides Base frequency of 4000 Hz, and sweep or beat frequency selection of 1 to 250 Hz thru Rotary Potentiometer (Knob). Also sweep time can be selected as 1/1, Continuous, 8/8 or 10/10. In TENS TS1211 provides pulse width selection from 50 to 250 Microseconds and Frequency from 2 to 150 Hz, along with 5 different modes and treatment time.

4. **DISPLAY**
INFREX and **TENS TS1211** have LCD (Liquid Crystal Display) for showing Treatment Mode, PW, PR, Treatment Time and battery status.
Predicate device IF-4000 has only LED indication to show ON/OFF and Low Battery Status.

5. **POWER**
INFREX works on rechargeable battery back up, so the treatment will not be limited to site near AC outlet and can be carried along. Similarly TENS TS1211 operates only on +9 Volts alkaline battery and IF-4000 operates on +9V alkaline battery or AC Adaptor option.

6. **RUBBER KEY PADS**
INFREX and **TENS TS1211** use Rubber key-pads, while Predicate Device IF-4000 use Mechanical Rotary Pots and Sliding switches for mode or frequency selection, which limits there life.

7. **CASING**
All three units are attractive and fitted in an ABS body enclosure. They are strong and sturdy. **INFREX** is more ergonomic designed.

SAFETY

1. Since INFREX operates only on Rechargeable battery, it makes it safer then its Predicate devices.

2. Rubber Key Pad is provided which is known to withstand longer than other mechanical methods and has much more life cycle.

3. Circuitry efficiency is good as matrix circuitry is used in keyboard & amplification circuitry is simple.

SUMMARY

INFREX has a self-contained safety circuit.

Open/short circuit performance: This **INFREX** functions normally after open and short circuited conditions between output jacks, with the device operating for maximum of 15 minutes, in each condition at the maximum available setting of pulse width, pulse rate and pulse amplitude.

A concise detailed design control activities, verification and validation activities is described in next section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2006

Johari Digital Healthcare Ltd.
c/o Pooja Johari
7131 Farralone Avenue, # 48
Canoga Park, California 91303

Re: K060246
Trade/Device Name: Infrex
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Codes: GZJ, LIH
Dated: April 21, 2006
Received: April 24, 2006

Dear Ms. Johari:

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) 276-0295. 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 Mark N. Melkerson
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): - K060246

Device Name: INFREX
INFREX is indicated to be used for: -

- Symptomatic relief and management of chronic intractable pain.
- Adjunctive treatment in the management of post surgical and post–traumatic, Acute pain condition.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060246

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)
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