MAY 29 2009

K090052

Johari Digital Healthcare Ltd.
ISO 13485 : 2003; 9001 : 2000, FDA USA Regd.
Electronic Hardware Technology Park (100% E.O.U. Unit)
G-582, G-583, EPIP PARK, BORANADA, JODHPUR - 342 001 (Raj.) INDIA
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Traditional 510(k) ANNEXURE 'IV'

SUMMARY

"Traditional 510(k)"

Submitter's Name	:	**JOHARI DIGITAL HEALTHCARE LTD.** Electronic Hardware Technology Park G-582, 583, E.P.I.P., Boranada, Jodhpur-342008
Phone	:	+912931281531/36 +912915132424
Fax	:	+912931281539
E-mail	:	nisha.johari@joharidigital.com
Contact person	:	Mrs. Nisha Johari
Date of Summary Submission	:	9th March, 2009
Resubmitting on	:	N.A.

Nisha Johari.

MRS. NISHA JOHARI
DIRECTOR MARKETING
JOHARI DIGITAL HEALTHCARE LTD.

NEW DEVICE FOR WHICH SUBMITTING

Trade Name	: **Cranial Electrical Nerve Stimulator**
Model Name	: **FM 10/C**
Common Name	: **CRANIAL ELECTROTHERAPY STIMULATOR AND TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR**
Classification Name	: **Neurology** (As Per 21 CFR Sections **882.5800, 882.5890**)

LEGALLY MARKETING DEVICE

CES ULTRA	:	**Cranial electrotherapy**
Manufacturer	:	NEURO-FITNESS LLC
Address	:	Neuro-Fitness, LLC 33631 SE. Redmond / Fall City Rd. #2, Fall City, WA 98024 Phone: 425-222-0830, Fax: 425-222-7413 Contact: Michael Stevens
ELECTRONIC PAIN RELIEVERS	:	**Transcutaneous Electrical Nerve Stimulator**
Manufacturer	:	JETCO OF AMERICA
Address	:	JETCO OF AMERICA 3003 WEST NORTHERN AVE., STE. 5 PHOENIX , AZ 85051

DESCRIPTION OF NEW DEVICE - FM 10/C

FM 10/C is portable Cranial Electrical Nerve Stimulator. FM 10/C combines uniquely two proven therapies CES for the treatment of insomnia, depression, or anxiety and TENS for symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain. Thus FM 10/C offers a partnership between Transcutaneous Electrical Nerve Stimulation (TENS) and Cranial Electrotherapy Stimulation (CES).

FM 10/C has three modes viz. (i) TENS Burst (ii) TENS Conventional and (iii) CES mode. It provides easy mode selection through slide switch and user can select any one of the available modes through it. TENS and CES modes will not operate simultaneously so, if CES Leads are inserted then TENS modes are automatically blocked for the user and vice versa.

TENS mode is programmable and user will have the option to select pulse width and pulse rate using analog pots. In addition treatment time is also selectable using a slide switch options available are 30 minutes, 60 minutes or continuous treatment time. FM 10/c is only battery operated, with low battery indication.

FM 10/C comes complete with all the necessary components of same quality and standards as being provided with Predicate Device CES Ultra and ELECTRONIC PAIN RELIEVERS to perform Electrical Stimulation. Below is a list of items that are included:

Sr. Number	Particulars	Quantity
1.	FM 10/C Unit	01 no.
2.	Round Electrode Lead Wire (2 pole, 116.5 cm, 4mm Diameter Plug)	02 nos.
3.	Ear Clip Electrodes (Surface Area 7.9 mm max) With Round Lead wire (2 Pole, 116.5 cm, 5mm Diameter Plug)	01 nos.
4.	Electrodes (Round 2")	04 nos.
5.	Electrode gel (250 ml)	01 tube
6.	Manual	01 no.

The electrodes are legally marketed in U.S., manufactured by:

WANDY RUBBER INDUSTRIAL CO, LTD.

NO.24 , ALLEY 37, LANE 392, FU TEH 1ST RD.,

HSI-CHIH 221, TAIPEI, TAIWAN

Unit FM 10/C is developed to combine the effects of two already established equipments in the market, described as below. The new device is safe and effective and does not introduce new questions of safety and effectiveness.

INTENDED USE

FM 10/C is indicated to be used for:

- CES for the treatment of insomnia, depression, or anxiety.
- TNS for Symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-traumatic and post-surgical acute pain.

TECHNICAL SPECIFICATION OF THE NEW DEVICE FM 10/C

S. No.	Description	New device
1.	**Power Source**	9 Volts Alkaline Battery
2.	**Waveform**	TENS: Asymmetrical Biphasic Square Wave. CES: Symmetrical Biphasic Square Wave.
3.	**Number of Outputs**	Three, 2 for TENS and 1 for CES
4.	**Number of Channels**	Three, 2 for TENS and 1 for CES
5.	**Max output Current**	TENS – 100 mA @ 500 Ohms Load CES – 1.5mA @ 2KOhms Load
6.	**Pulse Width**	TENS: 40 µS to 250 µS [Selectable] CES: 500 µS
7.	**Pulse Rate**	TENS: 1 Hz to 140 Hz [Selectable] CES: 100 Hz
8.	**Treatment Time**	Selectable 30 minutes, Continuous, 60 minutes
9.	**Maximum Phase Charge**	TENS: 25 µC CES: 0.75 µC @ 2 KΩ
10.	**Maximum Current Density**	TENS: 0.172 mA / cm^2 @ 500 Ω CES: 3.07 mA/cm^2 @ 2KΩ
11.	**Maximum Power Density**	TENS: 8.6 mWatt / cm2 @ 500 Ω CES: 9.19mWatt/ cm^2 @ 2 KΩ

TECHNICAL SPECIFICATION OF THE PREDICATE DEVICES

S. No.	Description	CES ULTRA	ELECTRONIC PAIN RELIEVERS
1.	**Power Source**	9 Volts Alkaline Battery	9 Volts Alkaline Battery
2.	**Waveform**	Symmetrical Biphasic Square Wave	Asymmetrical Biphasic Square Wave.
3.	**Number of Outputs**	One	Two
4.	**Number of Channels**	One	Two
5.	**Max output Current**	1.5mA @ 2KOhms Load	100mA @ 500 Ohms Load
6.	**Maximum Phase Charge**	0.75 µC @ 2 KΩ	25 µC @ 500 Ohms.
7.	**Maximum Current Density**	3.07 mA/cm^2 @ 2KΩ	0.172 mA / cm^2 @ 500 Ω
8.	**Maximum Power Density**	9.19mWatt/ cm^2 @ 2 KΩ	8.6 mWatt / cm2 @ 500 Ω

TECNOLOGIAL CHARACTERISTICS

1. MICRO-CONTROLLER

FM 10/C 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, ELECTRONIC PAIN RELIEVERS and CES ULTRA also use a micro controller.

2. MULTICHANNEL

FM 10/C has three outputs. Two dedicated for TENS and one output dedicated for CES. ELECTRONIC PAIN RELIEVERS has only two channels. CES ULTRA has only one channel dedicated for CES.

3. MULTIWAVE SELECTIONS & PROGRAMABILITY

FM 10/C produces selection of TENS and CES. TENS mode has selection of Pulse Width from 40 µS to 250 µS and Pulse Rate from 1 to 140 Hz for pain relief. CES is of Fixed Pulse Width 500 µS and Pulse Rate 100 Hz. Patient can also option of three treatment times 30 minutes, 60 minutes or continuous, which is selectable through slide switch.

ELECTRONIC PAIN RELIEVERS has three modes and has selection of Pulse Width from 40 µS to 250 µS and Pulse Rate from 1 to 140 Hz for pain relief

CES ULTRA is meant only for CES, and produces micro current with 100 Hz frequency. Two treatment times can be selected thru switch viz 30 minutes or 45 minutes.

4. DISPLAY

FM 10/C uses stickers and markings on enclosure, for user to see the parameters which he has selected. Low battery and Power ON are indicated thru LED.

ELECTRONIC PAIN RELIEVERS uses stickers and markings on enclosure, for user to see the parameters which he has selected. Low battery and Power ON are indicated thru LED.

CES ULTRA uses stickers and markings on enclosure, for user to see the parameters which he has selected.

5. POWER

FM 10/C, ELECTRONIC PAIN RELIEVERS and CES ULTRA is use +9V alkaline battery.

6. KEY PADS

FM 10/C uses Rotary Pots for pulse width, pulse rate & intensity and Sliding switches for mode & treatment time selection.

ELECTRONIC PAIN RELIEVERS uses Rotary Pots for pulse width, pulse rate & intensity and Sliding switches for mode Selection..

CES ULTRA uses rotary Pot for Intensity Control and a Tack switch for time selection.

7. CASING

All three units are attractive and fitted in an ABS body enclosure. They are strong and sturdy. **FM 10/C** is more friendly and ergonomic designed.

SAFETY

1. Since FM 10/C operates only on battery, it makes it safe.
2. TENS mode is disabled once CES electrode Lead is inserted, which makes it more safe to use.

SUMMARY

FM 10/C 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 are described in next section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Johari Digital Healthcare Ltd.
% Mrs. Nisha Johari
Electronic Hardware Technology Park
G-582, 583, E.P.I.P., Boranada
Jodhpur, Rajasthan
India 342008

MAY 29 2009

Re: K090052
Trade/Device Name: Cranial Electrical Nerve Stimulator (FM 10/C)
Regulation Number: 21 CFR 882.5800
Regulation Names: Cranial electrotherapy stimulator
Regulatory Class: III
Product Code: JXK, GZJ
Dated: May 22, 2009
Received: May 27, 2009

Dear Mrs. 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 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.

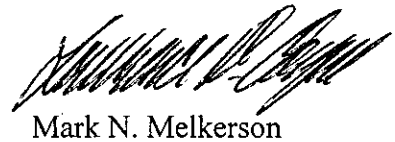
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/cdrh/comp/ 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



FOR Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Johari Digital Healthcare Ltd.
ISO 13485 : 2003; 9001 : 2000, FDA USA Regd.
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E - mail : sales@joharicare.com :: info@joharidigital.com
Website : joharidigital.com

Indications for Use
510(k) Number (if known): K090052
Device Name: Cranial Electrical Nerve Stimulator (FM 10/C)

FM 10/C is indicated to be used for:

- CES for the treatment of insomnia, depression, or anxiety.
- TENS for Symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-traumatic and post-surgical acute pain.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090052

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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