TONE-A-MATIC®

510(k) Summary

Submitter's Name	: TONE-A-MATIC INTERNATIONAL INC.
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Date of Summary Submission	: April 28, 2014
Resubmitting on.	: N.A.

Name of Person and Signature
(Ms. ANNIA KORDIUK-Operations Manager)

NEW DEVICE FOR WHICH SUBMITTING

Common or Usual Name	**:POWERED MUSCLE STIMULATOR.** **MUSCLE STIMULATOR** **TRANSCUTANEOUS ELECTRICAL NERVE STIMULATIOR FOR PAIN RELIEF**
Classification name	: **Powered muscle stimulator** **(21 CFR 890.5850, Product Code IPF)** **And** **Transcutaneous electrical nerve stimulator for pain** **(21 CFR 882.5890, Product Code GZJ)**
Trade Name	**:Tone-A-Matic**
Model Name of Device	**:TDR 68**

LEGALLY MARKETED DEVICE

Winstim	: Ultrasound and Powered Muscle Stimulator
Classification Name	**: Ultrasound and Muscle stimulator**
510(k) Number :	: K102190
Manufacturer	:Johari Digital Healthcare Ltd.
Address	:Electronic Hardware Technology Park G-582, 583,E.P.I.P., Boranada Jodhpur (Rajasthan)-342008 INDIA

DESCRIPTION OF NEW DEVICE Tone-A-Matic

The **Tone-A-Matic** is a Tone-A-Matic Device is Non-TRANSIT-OPERABLE and PORTABLE micro-controller operated device not to be Worn by patient. It generates electrical impulses and effectively transfers your desired choice of these pre-programmed electrical impulses directly through the electrode adhesive pads to the suggested area of the body where the electrodes are placed. **Tone-A-Matic** was developed based on physics, electro biology and modern micro-electronic technology. You will be more than pleased with this state-of-the-art device.

The **Tone-A-Matic** is very user friendly with a large liquid crystal display (LCD) screen that displays the treatment mode in use, a countdown timer and battery indicator. The intensity of the treatment can be increased or decreased by Keypads. User can set the time of the treatment from available choice of 1 min. to 60 min.

It is a clinical model with easy user interface and versatility to treat different body areas simultaneously. This aesthetically designed clinical model has 3 selectable modes(Russian, TENS, EMS) and treatment parameters. The state of the art **Tone-A-Matic** is light weight (1.78 Kg), small in size (10.3" X 7.5" X 3.5", LxWxH) and battery powered which allows it to be easily moved to any location for immediate use.

Tone-A-Matic comes complete with all the necessary components of same quality and standards as being provided with predicate device **Winstim**. Below is a list of items that are included:

ACCESSORIES LIST

S No.	Particulars	Quantity
1.	Electrode Cable (2Pin)	08 nos.
2.	Self Adhesive Electrodes	16 nos.
3.	Adaptor with AC Cord	01 no.
4.	Instruction Manual	01 no.

INTENDED USE OF NEW DEVICE Tone-A-Matic

Tone-A-Maticis indicated to be used for

- **Russian and EMS for:**
  - Relaxation of muscle spasms
  - Prevention or retardation of disuse atrophy
  - Increase local blood circulation
  - Muscle re-education
  - Maintaining or increasing range of motion
  - Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.
- **TENS for:**
  - Symptomatic relief of chronic, intractable pain.
  - Management of pain associated with post-traumatic or post-operative conditions.

DESCRIPTION OF PREDICATE DEVICE Winstim

The product, is standalone, portable electric and ultrasound stimulator, used in physiotherapy for rehabilitation and pain relieving purposes. The physiotherapist will be able to program the unit and initiate stimulation application through touch-screen panel interface. The configured stimulation then can be applied through in-built electro stimulator module or peripheral ultrasound head. The unit can be powered up through external AC adapter, in addition to portable (re-chargeable) battery-driven operation. Units are supplied with electrodes listed in 510(k) K050469, typically 2X2 inch.

INTENDED USE OF PREDICATE DEVICE Winstim

- **Russian and EMS for:**
  - Relaxation of muscle spasms
  - Prevention or retardation of disuse atrophy
  - Increase local blood circulation
  - Muscle re-education
  - Maintaining or increasing range of motion
  - Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.
- **TENS for:**
  - Symptomatic relief of chronic, intractable pain.
  - Management of pain associated with post-traumatic or post-operative conditions.

TECHNICAL SPECIFICATION OF NEWD DEVICE Tone-A-Matic

S.No.	Description	New Device Tone-A-Matic
1.	Power Source	24 VDC Adaptor and rechargeable battery operated
2.	Waveform	1. RUSSIAN - Square Wave 2. TENS – Square Wave 3. EMS – Square Wave
3.	Maximum Output Voltage	1. RUSSIAN - 50 Vpp @ 500Ω 60Vpp @2KΩ 2. TENS – 57 Vpp @ 500Ω 90Vpp @2KΩ 3. EMS – 57 Vpp @ 500Ω 90Vpp @2KΩ
4.	Maximum Output Current	1. RUSSIAN - 100 mA pp @ 500Ω 30mA pp @ 2KΩ 2. TENS – 114 mA @ 500Ω 45mA pp @ 2KΩ 3. EMS – 114 mA pp @ 500Ω 45mA pp @ 2KΩ
5.	Number Of Output	8
6.	Number of Output Channels Synchronous or Alternating?	Synchronous (a) Channel 1 and 2 are completely isolated. Only power supply and ground are common Confirms to ANSI 3.2.3.2
7.	Net Charge	1. RUSSIAN - 0 μC 2. TENS – 0 μC 3. EMS – 0 μC
8.	Maximum Phase Charge	1. RUSSIAN - 20.00 μC 2. TENS – 22.5 μC 3. EMS – 22.5 μC
9.	Maximum Current density	1. RUSSIAN - 3.87 mA/cm2 @ Load of 500 Ohm 2. TENS – 4.41 mA / cm2 @ Load of 500 Ohm 3. EMS – 4.41 mA / cm2 @ Load of 500 Ohm
10.	Maximum Power Density	1. RUSSIAN - 0.193 Watt/cm2 @ Load of 500 ohm 2. TENS – 0.251 Watt / cm2 @ Load of 500 Ω 3. EMS – 0.251 Watt / cm2 @ Load of 500 Ω

11.	Treatment Time	1 – 60 MINUTES

TECHNICAL SPECIFICATION OF THE PREDICATE DEVICE Winstim

S.No.	Description	PREDICATE DEVICE Winstim (K102190)
1.	Power Source	24 VDC Adaptor and rechargeable battery operated
2.	Waveform	1. RUSSIAN - Sinusoidal 2. TENS – Square Wave 3. EMS – Square Wave
3.	Maximum Output Voltage	1. RUSSIAN - 50 Vpp @ 500Ω 2. TENS – 57 Vpp @ 500Ω 225 Vpp @ 2KΩ 3. EMS – 57 Vpp @ 500Ω 225 Vpp @ 2KΩ
4.	Maximum Output Current	1. RUSSIAN - 100 mA @ 500Ω 2. TENS – 114 mA @ 500Ω 112.5 mA @ 2KΩ 3. EMS – 114 mA pp @ 500Ω 112.5 mA @ 2KΩ
5.	Number Of Output Modes	7
6.	Number of Output Channels Synchronous or Alternating?	Synchronous (a) Channel 1 and 2 are completely isolated. Only power supply and ground are common (b) Electrotherapy and Ultrasound are also isolated. They have their own Hardware, which are completely isolated. Confirms to ANSI 3.2.3.2
7.	Net Charge	1. RUSSIAN - 0 μC 2. TENS – 0 μC 3. EMS – 0 μC
8.	Maximum Phase Charge	1. RUSSIAN - 20.00 μC

		2. TENS – 22.5 μC 3. EMS – 22.5 μC
9.	Maximum Current density	1. RUSSIAN - 3.87 mA/cm2 @ Load of 500 Ohm 2. TENS – 4.41 mA / cm2 @ Load of 500 Ohm 3. EMS – 4.41 mA / cm2 @ Load of 500 Ohm .
10.	Maximum Power Density	1. RUSSIAN - 0.246 Watt/cm^2 @ Load of 500 Ohms 2. TENS – 0.064 Watt/cm^2 @ Load of 500 Ohms 3. EMS – 0.064 Watt/cm^2 @ Load of 500 Ohms
11.	Treatment Time	1 – 100 MINUTES

INTENDED USE:

Tone-A-Matic is indicated to be used for

- **Russian and EMS for:**
  - Relaxation of muscle spasms
  - Prevention or retardation of disuse atrophy
  - Increase local blood circulation
  - Muscle re-education
  - Maintaining or increasing range of motion
  - Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.
- **TENS for:**
  - Symptomatic relief of chronic, intractable pain.
  - Management of pain associated with post-traumatic or post-operative conditions.

SUBSTANTIAL EQUIVALENCE:

The electrical stimulation provided by the Tone-A-Matic device is similar to that of Predicate Device Winstim. The electrical pulses transmitted in different modes are restricted in amplitude and duration to values consistent with that of the predicate device quoted above in electrical parameter comparisons. User safety has been taken into account while designing the Tone-A-Matic device.

The differences that exist between these devices are insignificant in the terms of safety or effectiveness.

NON-CLINICAL TESTS PERFORMED:

Tone-A-Matic complies with international standards for electrical safety and electromagnetic compatibility. Compliance to applicable voluntary standards includes IEC 60601-1. Ed3.0, IEC 60601-1-2, IEC 60601-2-10,IEC 60601-1-11 and ISO 14971: 2007. Comprehensive risk analysis has been carried out for the device with regards to safety and effectiveness. Addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

CONCLUSION:

The electrical stimulation provided by the Tone-A-Matic device is similar to that of Predicate Device Winstim.

The Tone-A-Matic has same intended use and similar technological characteristics as its FDA cleared predicate devices. Moreover the verification and validation tests contained in this submission demonstrate that the differences in the Tone-A-Matic still maintain the same safety and effectiveness as that of the cleared predicate. In other words, those engineering differences do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Safety concerns regarding proper use of electrodes and electrode pads placement have been fully addressed by making the user conscious of the proper placement of electrodes and proper operations of the device through detail in the User's Instruction Manual.

Material Used in Tone-A-Matic Device which will come in contact with the patient

1) Enclosure Made up of ABS Material
2) Lead wire Made up of PVC material
3) Electrodes : 2" X 2" square self adhesive 510(K) cleared , K002227

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Johari Digital Healthcare, Ltd.
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Jodhpur, Rajasthan, 342008 India

MAR 17 2011

Re: K102190
Trade/Device Name: WinStim
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and muscle stimulator
Regulatory Class: Class II
Product Code: IMG, GZJ, IPF, GZI
Dated: February 14, 2011
Received: February 14, 2011

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. 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,

/S/

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

Enclosure

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Indications for Use

510(k) Number (if known): K102190

Device Name: WinStim

Indications For Use:

☐ **Russian and High Volt and EMS for:**

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.

☐ **Interferential, Premod and TENS for:**

- Symptomatic relief of chronic, intractable pain.
- Management of pain associated with post-traumatic or post-operative conditions.

☐ **Ultrasound for:**

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:

- Pain Relief
- Reduction of muscle spasms
- Joint contractures

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102190