

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.90(e).

1.0 Submitter Information

Establishment Registration Name and Number:

SAVIA LTD.
4th Industry District, Fenghuang, Fuyong County, Baoan
Shenzhen, Guangdong 518103
China
Registration Number: 3007752599

Contact Person (US Agent/Official Correspondent) of the Applicant:

Mr. Guenter Ginsberg
(President)
Media trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, FL 34135
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Device Information

Basis:	New device
510(k) submission type:	Traditional
Device Common Name:	Transcutaneous Electrical Nerve Stimulator
Trade Name:	Savia OTC TENS Device
Model:	EM-38
Classification Name:	TENS Device
Review Panel:	Neurology
Product Code:	NUH
Regulation Class:	Class II
Regulation Number:	882.5890

2.0 Predicate device Information

Sponsor: Well Life-Healthcare LTD.
Device: OTC TENS for Back Pain Relief, Model WL-2407
510(k) No: K063660

3.0 Device Description

The Savia OTC TENS Device, Model EM-38 is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

The EM-38 is a selectable dual channel TENS device operated by 4.5 V (3xAAA-Alkaline batteries). It comes with a convenient belt that features 4 sewn-in permanent electrodes and build-in wires and a receptacle for the control unit.

There are 4 selectable pre-programmed output waveforms to choose from and the intensity levels are adjustable from 0 to 152 mA. Running times can be adjusted from 22 to 31 min. Other information displayed on the LCD display are operation mode, output waveform (programs) output strength, time remaining and battery low warning. A lock function provides extra safety for the user.

4.0 Intended Use

The Savia OTC TENS Device, Model EM-38 is intended for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

The standard format for the statement of indications and contradictions for use are provided hereafter.

5.0 Performance Summary

Testing of the Savia OTC TENS Device, Model EM-38 includes functional performance testing and electrical safety testing. The device is manufactured to comply with the following international standards:

EN 60601-1, Medical Equipment – part 1: General Requirements for Safety,
1990+A1;1993+A2;1995+A13;1996

EN 60601-1-2; 2007

EN 60601-1-4; 1996+A1;1999

EN 60601-1-6;2004

EN 60601-1-2-10;2000+A1;2001

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance. Furthermore it was demonstrated by a Usability Study that the labeling was sufficient for users to operate the device safely.

6.0 Comparison to predicate device and conclusion

Compared with the predicate device, the Well-Life Model WL-2402, the Savia OTC TENS Device, Model EM-38, has the same intended use and similar technological characteristics. The differences between the two devices are minimal and do not present any safety and effectiveness issues.

It is therefore concluded that the Savia OTC TENS Device, Model EM-38 is substantially equivalent to the predicate device.

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? ^A		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? ^A	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X



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

SEP 4 2012

Savia Ltd.
c/o Mr. Guenter Ginsberg
President
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, Florida 34135

Re: K113321

Trade/Device Name: TENS Back Pain Relief System, Model EM-38
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: August 17, 2012
Received: August 24, 2012

Dear Mr. Ginsberg:

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,


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

Indications for Use Form

510(k) Number (if known): K113321

Device Name: SAVIA OTC TENS Model EM-38

Indications for Use:

The intended use of the SAVIA OTC TENS unit Model EM-38 is for the relief of pain associated with sore or aching muscles of the lower back due to strain from exercise or normal household and work activities.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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