K071878

# Med-Lectric Corporation

## 510 (k) Summary

**Submitter's Identifications**
**Manufacturer and Sponsor**

Med-Lectric Corp.
1909 Lawrence Road # 100
Kemah, TX 77565 USA.
Date of Summary Preparation: November 24, 2007

DEC 07 2007

**Contact**
M. Lee Gunter
Telephone: 281-334-5166
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**Trade Name of Devices**

**Delta Scanner™, Delta Scanner Pro™, DS Low Back Pro™, DS Sports Pro™, DS Rehab™**

**Common name**

TENS device

**Classification**
**21 CFR 882.5890, GZJ, Class II, Transcutaneous Electrical Nerve stimulator**

**Information of the 510(k) Cleared Devices (Predicate Devices)**

InterX5000™, K042912, K053626 17/May/2005

Body-Stim™, Biomodulator™, Best-RSI™, Best Pro™,
K062641, May 30, 2007

**Description and Intended Use**

Delta Scanner devices are micro-current transcutaneous electro-stimulation devices for symptomatic relief and management of chronic, intractable pain, and as adjunctive treatment in the management of post-traumatic and post surgical pain. They are handheld, easy-to-use battery operated portable devices, for use in the home or clinic.

The technological characteristics of these devices, including waveforms, outputs, and impedance sensing functions are the same as the InterX 5000™ and the Avazzia Best Pro™

The software verification has been conducted according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices-- Guidance for Industry and FDA Staff. May 11, 2005.

**Conclusions**

The devices have intended uses and technological characteristics that are substantially equivalent to the predicate devices. Moreover, verification and validation tests contained in this submission demonstrate that the submitted models are equivalent to the safety and effectiveness as that of the cleared devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2007

M. Lee Gunter
Med-Lectric Corporation
1909 Lawrence Road, #100
Kemah, Texas 77565

Re: K071878
Trade Name: Delta Scanner™, Delta Scanner Pro™, DS Low Back Pro™, DS Sports Pro™, DS Rehab™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: October 9, 2007
Received: October 17, 2007

Dear Mr. Gunter:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Mark N. Melkerson

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: K071878

Device name: Delta Scanner™, Delta Scanner Pro™, DS Low Back Pro™, DS Sports Pro™, and DS Rehab™

Indications for use:
For symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and posttraumatic acute pain.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

**(Division Sign-Off)**

**Division of General, Restorative, and Neurological Devices**

Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) Number** K071878