AUG 22 2008 K081075

Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:
NanoVibronix Ltd.,
47 Hataasia St. P.O.B. 515
Nesher 36603, Israel
Tel: +972.4.820.1994; Fax:+972.820.2794
e-mail: harold@nanovibronix.com

Name of the Device: PainShield™ MD.

Predicate Devices: The PainShield™ MD is substantially equivalent to the Duo-Son Ultrasonic Diathermy Device manufactured by Orthosonics Ltd., subject of k970131.

Description of the Device: The PainShield™ MD is an ultrasonic diathermy device used to apply deep heat to tissues in the body with a transducer/applicator that is incorporated into a patch that adheres to the skin, as does a bandage.The PainShield™ MD is used to generate continuous wave ultrasound at 90 kHz, through a reusable applicator/transducer that covers an area of about 6 cm^2. The small applicator allows treatment of less accessible body parts such as, for example, the heel, the achilles tendon and the wrist. The device includes the above-mentioned transducer, a small, rechargeable, battery-powered driver unit and a cable that connects the driver to the transducer.

The Painshield™ MD device maintains the functionality of existing ultrasonic diathermy devices and also has the following advantages:

1. Small external dimensions and light weight,
2. User-friendly construction,
3. Because the applicator patch self-adheres to the skin, the physician's or therapist's hands are freed and he/she does not need to concentrate on and personally hold the applicator adjacent to the patient's body during the treatment session,
4. The low energy levels assure no overheating of the underlying tissue,
5. The applicator has an increased local concentration of ultrasound energy transfer due to the fixed adherence of the applicator to the treatment area,
6. Device characteristics assure that the operator is not exposed to therapeutic ultrasound,
7. Device characteristics, i.e., weight, dimensions and self-adherence, allow a patient to go about his/her normal daily activities while receiving treatment, as prescribed by the physician.

The Painshield™ MD complies with the FDA standard for ultrasonic therapy products.

April 14, 2008 — Date

Harold Jacob — Dr. Harold Jacob, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 5, 2014

NanoVibronix Ltd.
c/o Dr. Eli M. Orbach
International Regulatory Consultants
POB 6718
Efrat 90435
Israel

Re: K081075
Trade/Device Name: PainShield™ MD
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: II
Product Code: PFW
Dated: June 1, 2008
Received: June 5, 2008

Dear Dr. Orbach:

This letter corrects our substantially equivalent letter of August 22, 2008.

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 contact 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. 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,

Joyce M. Whang -S

for Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use (separate page):

510(k) Number (if known) K081075

Device Name The PainShield™ MD

Indications For Use:

The PainShield™ MD diathermy device is intended to apply ultrasounic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over The Counter Use No
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K081075