K061516

510(k) Summary

Compex Technologies Inc. Staodyn® Max preset TENS Device

510(k) Number 061516

Date of Summary Preparation:
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Submitter/Contact Person:

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Regulatory Affairs
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Device Name and Classification:
Trade Name: Staodyn® Max Preset
Common Name: Transcutaneous Electrical Nerve Stimulator
Classification Name: TENS device
Product Code: GZJ, NYN
Classification: Class II – 21CFR 882.5890

Manufacturing Location:
OEM: Tyece, Ltd.
Establishment Registration Number: N/A
Room 502-3, Po Hing Centre
18 Wang Chiu Road, Kowloon Bay
Hong Kong
Telephone: 852-2349-7456
Fax: 852-2349-9166

Axelgaard MFG. Co. LTD.
Establishment Registration Number: 2025066
329 West Aviation Rd.
Fallbrook, CA 92028
Tel: 720-723-7554
Fax:

COMPEX Technologies
Establishment Registration Number: 2126518
1811 Old Highway 8

New Brighton, MN 55112
Tel: 651-389-0771
Fax: 651-638-0477

Predicate Devices:
American Imex Premier Plus –K032003

Intended Use:
The Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device is used for the symptomatic relief and management of chronic intractable pain and relief of pain associated with arthritis. It is also used as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

Device Description:
The Staodyn® Max Preset is a Transcutaneous Electrical Nerve Stimulator (TENS) that transmits small electrical pulses through the skin to the underlying peripheral nerves. It is battery operated using 3-AAA batteries and includes two controllable output channels. It generates and delivers electrical impulses whose duration, rate and modulation can be altered by selection of 24 preset programs. The amplitude of the impulses can be increased or decreased with the use of two intensity toggle buttons, one for each output channel. The device has an on/off button that enables the device to be turned on or off. In addition, the on/off button can be used to pause a treatment program during use. The stimulator is housed in a molded portable plastic case with a viewable LCD display, accessible keypad, and accessible battery storage compartment.

Comparison to predicate:
The Staodyn® Max Preset TENS is substantially equivalent to the IMEX Premier Plus TENS device. The function, performance, and intended use of the Staodyn® Max Preset device is very similar to the Premier Plus. Both systems are designed to relieve pain. The outputs are virtually identical. Each can produce a symmetric biphasic pulse with peak voltage up to 50 Volts on 500 ohms load. Both devices allow the user to select preset programs and set the intensity from 1 to 20 by using a keypad and LCD display of the devices. Both devices have the ability to detect when the lead were open and have Auto shut off feature.

Non-clinical Testing:
Verification of the Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device includes electrical and mechanical tests to show that the device meets its product specifications over a range of operating and storage conditions. Validation testing for the Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device includes testing to show the device meets user needs according to marketing requirements.

Clinical Testing:

The Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device does not require clinical testing in order to determine substantial equivalence to the predicate devices.

Conclusion:
The non-clinical testing demonstrates that the Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device is safe, effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Carl Beaurline
Vice President, Regulatory Affairs
Compex Technologies, Inc.
1811 Old Highway 8
New Brighton, Minnesota 55112

FEB 6 2007

Re: K061516
Trade/Device Name: Staodyn® Max Preset, Model 4470
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Codes: GZJ, NYN
Dated: December 7, 2006
Received: December 8, 2006

Dear Mr. Beaurline:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indication for Use Statement

Indications for Use

510(k) Number (if known): K061516

Device Name: The Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device

Indications for Use:

The Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device is used for the symptomatic relief and management of chronic intractable pain and relief of pain associated with arthritis. It is also used as an adjunctive treatment in the management of post-surgical and post-traumatic 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K061516