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

January 21, 2015

Neurolumen, LLC
% Mr. Andy Thompson
Systec Engineering, LLC
P.O. Box 1123
Euless, Texas 76039

Re: K142025
Trade/Device Name: Neurolumen PN-1000
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY, GZJ
Dated: December 17, 2014
Received: December 18, 2014

Dear Mr. Thompson:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142025

Device Name

Neurolumen PN-1000

Indications for Use *(Describe)*

The Neurolumen is indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

The Neurolumen is also indicated for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-traumatic acute pain.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section C

510(k) Summary

12/12/2014

Contact Information:

510(k) Owner	510(k) Submitter
Neurolumen, LLC 9636 N. May Ave, Suite 230 Oklahoma City, OK 73120 405-463-6525 phone 405-463-6528 fax Doug Durning doug@neurolumen.com	Systec Engineering, LLC dba Systec Innovative Technologies, LLC PO Box 1123 Euless, TX 76040 817-864-9197 phone 817-684-1019 fax Andy Thompson andy@systeceng.com

Device Identification:

Trade Name: Neurolumen PN-1000
Regulatory Class: II
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Product Code: ILY, GZJ

Claiming Equivalence to:

Trade Name: NeurolumenPN
510(k) Number: K082223
Regulatory Class: II
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Product Code: ILY, GZJ

Trade Name: TerraQuant MQ2000 and HandyRx Laser MQ2007
510(k) Number: K061614
Regulatory Class: II
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Product Code: ILY, GEX

Trade Name: TerraQuant MQ2000 with TQ-1TENS

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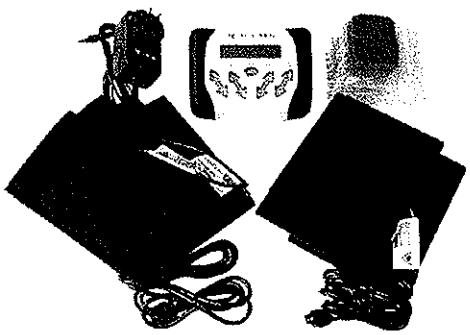
510(k) Number: K071445
Regulatory Class: II
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Product Code: ILY, GEX, GZJ

Trade Name: ComboCare 2000
510(k) Number: K081141
Regulatory Class: II
Regulation Number: 21 CFR 890.5500
Regulation Name: Transcutaneous electrical nerve stimulation for pain relief.
Product Code: GZJ, NHN, ISA

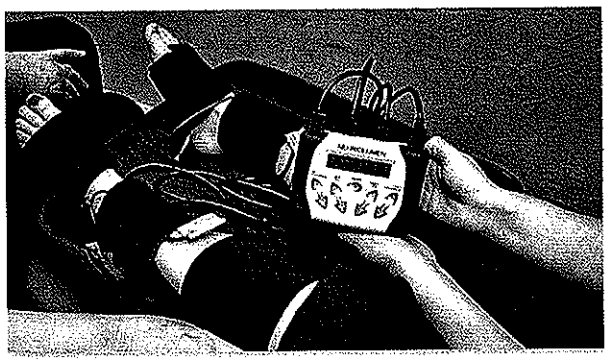
Device Description:

The Neurolumen is a medical therapy device that delivers Transcutaneous Electrical Nerve Stimulation (TENS) and Low Level Laser Therapy (LLLT) to a patient's limbs.

The Neurolumen consists of a control unit and six wraps. Each wrap contains two laser diodes, 4 light emitting diodes, and one or two TENS gel pads. After applying the wraps to the feet, ankles, and legs, the control unit is able to provide up to 30 minutes of therapy on a single charge of the internal lithium-ion battery. A charger is provided for recharging the internal battery.



PN-1000 Components



PN-1000 Typical Usage

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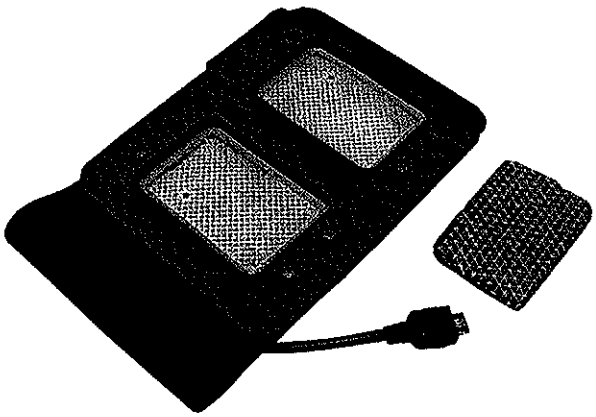
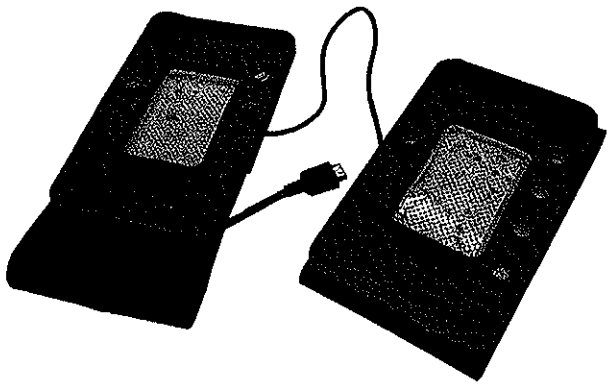


PN-1000 Leg Wrap with Gel Pad



PN-1000 Foot/Ankle Wrap

Unit	
Model	Neurolumen PN-1000
Part Number	0904000-00
Battery	Lithium-Ion 3.6V
Charger	220/110 VAC, 50/60Hz input 9VDC 1.5A output
Laser Diodes	
Quantity per wrap	2
Wavelength	808nm
Output Power	1mW
LEDs, Red	
Quantity per wrap	2
Wavelength	660nm
Output Power	90μW
LEDs, IR	
Quantity per wrap	2
Wavelength	940nm
Output Power	22μW
TENS (Load Impedance 500-550 ohms)	
Frequency	2 Hz
Output Current	100mA max
Pulse Voltage	75VDC max
Pulse width	100us biphasic

Intended Use:

The Neurolumen is indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

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The Neurolumen is also indicated for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-traumatic acute pain.

There are no changes to the intended use from the predicate device.

Comparison of technological characteristics:

Characteristic	Predicate Device	Neurolumen PN-1000
Control circuit	K082223: Digital circuit	Microcontroller. A 8-bit microcontroller was added to drive a newly added user interface, monitor the device functions, and generate the TENS pulse timing.
Liquid Crystal Display	K082223: Not present K071445: Present	Added to display TENS intensities, battery status, and therapy countdown timer.
Firmware	K082223: Not present K071445: Present	Added for microcontroller. Firmware developed per the FDA guidance document on medical devices containing software.
Battery	K082223: 4 AA NiMH batteries	1 Li-Ion battery pack added for improved charge density and cycle life.
TENS Pulse	K082223: Pulse width: 100us biphasic. Frequency: 2 Hz repetition rate. Current: 100mA max.	Identical
Laser Classification	K082223: Not present K061614: IIIa	Laser classification testing to IEC 60825-1 rated laser and LED output at class 3R (IIIa). Equivalent to other predicate devices cleared as non-heating lamps.
Laser Diodes	K082223: Not present K061614: 905nm K071445: 905nm	808nm
Red LEDs	K082223: 660nm	660nm

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	K061614: 680nm K081141: 640nm K071445: 660nm	
IR LEDs	K082223: 905nm K061614: 840nm K081141: 870nm K071445: 875nm	940nm

The determination of substantial equivalence is derived from the fact that the new device is based on the predicate device with improvements to the user interface and laser diode. It contains the same basic construction in the control unit and wrap assemblies, contains the identical TENS output waveform, and contains the same basic types of LED/laser diode outputs as predicate devices.

The New Device has been fully tested to national and international safety standards for medical devices, including IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-10, and IEC 60825-1.

Device Testing Results

The laser diodes were tested on three subjects to demonstrate that the device is able to raise the skin temperature between 40-45 degrees C for at least 10 minutes. The testing results confirmed that the unit is capable of raising and maintaining these temperatures.