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JAN 2 4 2014

K132057

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

11 September 2013

SUBMITTED BY: DYNATRONICS CORPORTATION
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Salt Lake City, UTAH 84121
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SUBMITTERS NAME: Douglas Sampson
VP, Operations and R&D
DYNATRONICS CORPORATION

1. DEVICE NAME:

Trade Name(s):	Dynatron® Peltier ThermoStim™
Common Name:	Combination Electrical Stimulation and Thermal Therapy probe
Classification:	Class II
Regulation Nos:	882.1320, 890.5720
Product Codes:	GXY, ILO

2. PREDICATE DEVICE:

Dynatron ThermoStim probe – K120835 (August 20, 2012)

3. DESCRIPTION:

The Dynatron Peltier ThermoStim probe is used to provide therapeutic electrical stimulation and thermal therapy treatments. The probe consists of a handle with a treatment head and connections to a Dynatron Solaris series controlling console for power and communications with a port for connection to electrical stimulation outputs. The probe acts as an electrode for therapeutic electrical current provided by a Dynatron Solaris device in the delivery of electrical stimulation therapy. The treatment head transfers thermal energy (hot or cold) supplied from a thermo-electric chip.

The probe is a passive, manual therapy accessory. Treatment cycles are controlled through previously cleared Dynatron Solaris series electrical stimulation devices.

The probe has a rectangular wedge treatment face of approximately 1¼" x 2¼" with rounded edges. The maximum surface area that could come in contact with a patient is approximately 38 cm^2.

4. INDICATIONS FOR USE:

A hand held cutaneous electrode to be used with Dynatronics Solaris devices to apply electrical stimulation and/or apply heat and cooling to the skin.

The Indications for Use stated in this submission match word for word the Indications for Use cleared for the predicate device.

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5. TECHNICAL ANALYSIS:

The Dynatron Peltier ThermoStim probe generates therapeutic benefits as described in allowed claims through the delivery of electrical stimulation and thermal energy to targeted tissues.

The probe allows the practitioner to manually apply various electrical stimulation treatments (limited to modalities available from the FDA cleared Dynatronics Solaris series devices) as well as thermal energy (hot or cold). The delivery of hot thermal energy has a targeted range of 90 – 112° Fahrenheit and the cold thermal energy has a targeted range of 39 – 60° Fahrenheit.

Performance Characteristics

The probe has a treatment face with a rectangular wedge shape and rounded edges. The treatment face is approximately 1¼" x 2¼" and the tip of the wedge is approximately ½" high. The probe acts as an accessory to provide the following electrotherapy options:

Biphasic, Russian, HiVolt, Interferential Current (IFC), Premodulated (IFC), and Microcurrent

The probe is designed to deliver thermal energy with the following range options.

Hot = 90 – 112° Fahrenheit
Cold = 39 – 60° Fahrenheit

Non-clinical Bench Testing

Wave forms of each electrotherapy output were captured from a Dynatron Solaris device through the Peltier ThermoStim probe and the predicate ThermoStim probe. Analysis of the wave forms for delivery of electrical stimulation treatments show no differences with the output from the predicate device compared to the subject device.

The Peltier ThermoStim probe will be tested for dielectric strength per EN60601-1 and for electromagnetic compatibility per EN60601-1-2. Per the March 2000 FDA Office of Device Evaluation guidance document "*Use of Standards in Substantial Equivalence Determinations*" these tests will be completed prior to marketing the device.

Thermal data was collected from the Peltier ThermoSTIM probe in "hot" and "cold" modes. Results showed temperatures consistently falling in the targeted thermal ranges.

Both devices use the Dynatron Solaris controlling console to deliver electrical stimulation through the probes as a cutaneous electrode. The electrotherapy wave form outputs from the predicate and subject are equivalent. Both probes provide heating and cooling in the same thermal ranges. Both probes have treatment areas large enough for a safe current density to mitigate risks of patient injury. Patient contact surfaces for both the predicate and subject probe are identical aluminum composition. From a non-clinical analysis we conclude that the two probes are substantially equivalent.

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6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

The Dynatron Peltier ThermoStim probe shares the same basic therapeutic characteristics, features and intended uses as the predicate probes.

	Predicate Dynatron ThermoStim Probes	**Dynatron Peltier ThermoStim Probe**
Intended Use	Cutaneous electrode with heating and cooling	Cutaneous electrode with heating and cooling
Target Populations	Patients with acute or sub-acute pain	Patients with acute or sub-acute pain
Dimensions (W x D x L)	1.5" x 1.5" x 11"	2"x3.6"x10"
Weight	125 grams	750 grams
Therapy Delivery	Electrical stimulation and/or thermal therapy (hot or cold) through contact with patient's skin	Electrical stimulation and/or thermal therapy (hot or cold) through contact with patient's skin
Electrical Stimulation	ThermoStim probe acts as a cutaneous electrode for the delivery of electrical stimulation to a patient from a Solaris device	Peltier ThermoStim probe acts as a cutaneous electrode for the delivery of electrical stimulation to a patient from a Solaris device
Handle Material	Polypropylene plastic	ABS plastic
Treatment Face Material	6061 Aluminum	6061 Aluminum
Treatment Face Options	Flat – 1.5" diameter – 11.4cm^2 Domed – 1.1" diameter – 12.3cm^2	Rectangular – 38 cm^2 surface
Current Density (gravity pressure)	Flat – 0.11W/cm^2 Round –0.20W/cm^2	0.08 W/cm^2
Power Density (gravity pressure)	Flat –4.4mA/cm^2 Round –8.3mA/cm^2	3.3mA/cm^2

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	Predicate Dynatron ThermoStim Probes	**Dynatron Peltier ThermoStim Probe**
Thermal Therapy	ThermoStim probe delivers hot or cold thermal therapy via water that is heated or cooled by Peltier thermo-electric chips in a reservoir and circulated to the face of the probe/electrode.	Peltier ThermoStim probe delivers hot or cold thermal therapy via a Peltier thermo-electric chip that is in contact with the treatment head of the probe/electrode
Thermal Range	Hot: 104-112F Cold: 36 – 50F	Hot: 90-112F Cold: 39 – 60F
Range of Skin Temperatures	Hot: 105.5 – 108.3°F Cold: 53.5 – 56.5°F	Hot: 90 – 110.5°F Cold: 44 – 60.5°F

It is our assessment that the Dynatron Peltier ThermoStim probe is substantially equivalent to the predicate Dynatron ThermoStim probes (applicable "K" number listed above) because both devices are labeled for the same Indications for Use, both deliver equivalent electrotherapy outputs, both deliver equivalent thermal outputs, and both are a hand held cutaneous electrode accessory controlled by a Dynatron Solaris console. The only distinction is the method by which the thermal energy is delivered and the shape of the electrode.

7. SAFETY AND EFFECTIVENESS SUMMARY:

There are no substantive differences between the product defined in this 510(k) submission and the predicate devices. This device is similar to the technology that is currently used in other similar medical devices. This device is subject to development and documentation as required in the Quality System Regulation, 21 CFR Part 820, under design/change control, and is subject to verification and validation to applicable standards / guidance documents. The sum of bench test results and design control outcomes allows us to conclude that the Dynatron Peltier ThermoStim probe is as safe and effective in delivering treatments when used as indicated in specific applications under a clinician's supervision / therapy program as the predicate probes.

Signed: _____ Dated: _____

Douglas Sampson, VP, Operations and R&D
DYNATRONICS CORPORATION

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 24, 2014

Dynatronics Corporation
Douglas Sampson
7030 Park Centre Drive
Salt Lake City, Utah 84121

Re: K132057
Trade/Device Name: Dynatron Peltier ThermoStim
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, ILO
Dated: December 21, 2013
Received: December 23, 2013

Dear Mr. Sampson:

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 L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine 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 on last page.

510(k) Number *(if known)*
K132057

Device Name
Dynatron Peltier ThermoStim

Indications for Use *(Describe)*
A hand held cutaneous electrode to be used with Dynatronics Solaris devices to apply electrical stimulation and/or apply heat and cooling to the skin.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

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