

510(k) Summary**JUL 25 2013**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitters Information:

Eric Joseph
Chattem, Inc.
1715 West 38th Street
Chattanooga, TN 37409
423-822-3268
eric.joseph@chattem.com
Prepared July 25, 2013

2. Device Identification:

Classification Name: Transcutaneous Nerve Stimulator.
Trade/Proprietary Name: SmartRelief
Classification: Class II (21 CFR 882.5890)
Product Code: NUH, NYN

3. Identification of Predicate Devices:

The Chattem SmartRelief is of comparable type and substantially equivalent to the following predicate device:

PDI Works Pain-Aid, K113037

4. Device Description:

The SmartRelief is a transcutaneous electrical nerve stimulator for relief of muscular pain and sold without prescription. Key to its use are specially shaped electrodes that allow an untrained person to properly place them on the body.

The device consists of a microprocessor and associated components powered by a coin cell and housed in a small plastic case.

The controls for the device consist of three buttons: A power button which turns the device on and off, an intensity increase button, and an intensity decrease button. This simple user interface is further augmented by distinctive shapes to allow the user to identify the controls even if they cannot see the device.

Contact to the body is made through self-adhesive electrodes. Electrical connection from the device to the electrode is made directly through snaps on the device and the electrode; no leadwires are used. The electrodes are designed with both conductive surfaces combined into a single piece. These electrodes are manufactured in various shapes to facilitate proper placement on the body.

5. Intended Use:

To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

6. Technological Characteristics

The table below summarizes the technological characteristics of the SmartRelief and the predicate device:

	SmartRelief (K131159)	Pain-Aid (K113037)
Intended Use	To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.
Power Source	3V lithium battery	3V lithium battery
Number of Outputs	1	1
Number of Output Modes	1	1
Treatment Timer	30 minutes, fixed	30 minutes, fixed
Output Waveform	Asymmetrical Biphasic	Asymmetrical Biphasic
Shape	Rectangular	Rectangular
Housing Materials and Construction	Molded Plastic	Molded Plastic
Weight	20 grams	20 grams
Dimensions (mm) [W x H x D]	64x38x13	64x38x13
Max Pulse Freq. (Hz)	100 Hz	100 Hz

Pulse Width (μsec)	30 - 220μsec	30 - 220μsec
Technology / Control System	Microprocessor Control, Battery Powered	Microprocessor Control, Battery Powered
Patient Connection	Self-adhesive Electrodes	Self-adhesive Electrodes
Safety	Limited Power, Simple User Interface	Limited Power, Simple User Interface
Compliance with Voluntary Standards	Yes EN60601-1 EN60601-1-2	Yes EN60601-1 EN60601-1-2

Comparison of actual output under various loads and operating parameters shows no difference in the SmartRelief and the predicate device. The only difference in the SmartRelief and the predicate device is aesthetics. The electrical design, output, function and safety characteristics are exactly the same.

7. Conclusions:

The Chattem SmartRelief has the same intended use, design, technological characteristics, output mode, output waveform, and safety standards complied with as the cleared device Pain-Aid (K113037). Testing confirmed the equivalence in performance, including output waveform, between the SmartRelief and the predicate device. Because the SmartRelief is only different from the predicate, cleared Pain-Aid device by cosmetic details in the plastic enclosure, no differences in safety or effectiveness exist.



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

July 25, 2013

Chattem, Inc
C/O Eric Joseph
Associate Director, Regulatory Affairs
1715 West 38th St.
Chattanooga, TN 37409

Re: K131159
Trade/Device Name: SmartRelief
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: NUH, NYN
Dated: April 23, 2013
Received: April 26, 2013

Dear Mr. Joseph:

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.

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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" (21 CFR 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,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131159

Device Name: _SmartRelief

Indications For Use:

To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.

To be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

<p>Victor Krauthamer -S 2013.07.25 12:25:59 -04'00'</p> <hr/> <p>(Division Sign Off) Division of Neurological and Physical Medicine Devices (DNPMD)</p> <p>510(k) Number: K131159</p>
