K063743

MAY 24 2007

510(k) Summary

Date prepared:	14 December 2006 / revised 2 April 2007
Applicant:	Shockim Enterprise Ltd. 2500 Wilshire Boulevard, Suite 1115 Los Angeles, CA 90057
Contact person:	Nicolaas C. Besseling, Consultant BesTech Consulting Services 28711 Jaeger Drive Laguna Niguel, CA 92677 949.466.7472 bestechconsulting@cox.net
Trade name:	Rhythm Touch Q 2-Way
Common name:	Stimulator, nerve, transcutaneous, for pain relief — Class: 2
Classification name:	Transcutaneous electrical nerve stimulator for pain relief — Product codes: GZJ, NUH
Predicate device:	BIOSTIM KIT, K050174
Device description:	The Rhythm Touch Q 2-Way is a dual channeled powered nerve stimulator. It electronically stimulates nerves. It comprises two main components, namely, an electronic stimulatory module which generates the required stimulation signals, and skin electrodes with lead wires. The product is supplied with two sets of electrodes, a belt to fix and hold the unit and the electrodes, an instruction manual, and a set of batteries. Power is derived from two AAA cells located in a compartment protected by a removable battery cover. The electrodes provided with this model have 510(k) clearance. They are rectangular, 1.5"x1.75" in size. The lead wires also have 510(k) clearance.
Intended use:	Temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.
Summary of the technological characteristics of our device compared to the predicate device:	The Rhythm Touch Q 2-Way and the predicate device have similar technological characteristics. The Rhythm Touch Q 2-Way does not pose any new or different safety hazards, and the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2007

Shockim Enterprise Ltd.
% BesTech Consulting Services
Mr. Nicolaas C. Besseling
Consultant
2500 Wilshire Boulevard, Suite 1115
Los Angeles, California 90057

RE: K063743
Trade/Device Name: Rhythm Touch Q 2-Way
Regulation Number: 21 CFR 888.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NUH
Dated: April 3, 2007
Received: April 9, 2007

Dear Mr. Besseling:

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.

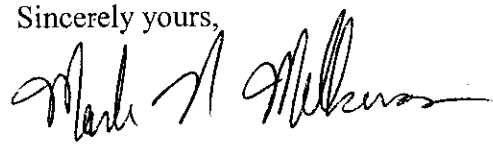
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21CFR 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/dsma/dsmamain.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

Indications for use

510(k) number (if known: K063743

Device name: Rhythm Touch Q 2-Way

Indications for use: Temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

Prescription use _____ and/or Over-The-Counter use √

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation

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

510(k) Number K063743