OCT 1 5 2003

Shockim Enterprises, Ltd.

2500 Wilshire Blvd. Suite 1165
Los Angeles, CA 900057
213-365-2279

510(k) SUMMARY

Submitter's name:	Shockim Enterprises, Ltd.
Address:	2500 Wilshire Blvd., Suite 1165 Los Angeles, CA 90057
Phone:	213-365-2279
Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821 greg@regulatoryspecialists.com
Date the summary was prepared:	July 15, 2003
Name of the device:	Rhythm Touch Q 2 - Way
Trade or proprietary name:	Rhythm Touch Q 2 - Way
Common or usual name:	Electrical muscle stimulation device
Classification name:	Power muscle stimulator (per 21 CFR section 890.5850)

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

BioStim Digital NMS, manufactured by BioMedical Life Systems. The clearance number is K010749.

Description of the device:

The Rhythm Touch Q 2-Way is a dual channeled powered muscle stimulator. It electronically stimulates muscles. 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 a set of single sided adhesive 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, which are provided with this model, have 510(k) clearance. They are 2" x 2" in size. The leadwires also have 510(k) clearance.

Intended use of the device:

Electrically powered devices intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

Indications For Use include:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

Summary of the technological characteristics of our device compared to the predicate device:

As was provided in both the Comparison and Standards sections, the Rhythm Touch Q 2-Way device and the BioStim device have similar technological characteristics and are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 5 2003

Shockim Enterprises, Ltd.
C/o Mr. Greg Holland
Regulatory Specialists, Inc.
3722 Avenue Sausalito
Irvine, CA 92606

Re: K032178
Trade/Device Name: Rhythm Touch Q 2-Way
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: July 14, 2003
Received: July 17, 2003

Dear Mr. Holland:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032178

Device Name: Rhythm Touch Q

Indications For Use:

Electrically powered devices intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

Indications For Use include:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use_____
(Optional Format 1-2-96)

for Mark N Melkerson

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

510(k) Number K032178