K032449

OCT 2 2 2003

510(k) SUMMARY

Migun Corporation's
Model HY5000
Thermassage Energy Product

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Submitter
John K. Purvis
Noninvasive Health Products, Inc.
1875 Fourteenth Avenue
Vero Beach, Florida 32960
Telephone: (561) 563-9800
Fax: (561) 564-9666

Sponsor
Migun Medical Instrument Co., LTD
Dae-Jun City
Dong-Ku, Yong-Jun Dong 68-21
South Korea
Phone: 82-42-222-3340
Fax: 82-42-623-0507

Contact Person
Edward A. Kroll
Representative Consultant for Migun Medical
Spectre Solutions, Inc.
5905 Fawn Lane
Cleveland, Ohio 44141
Phone: (440) 546-9810
Fax: (330) 253-4374

Date Prepared: August 5, 2003

Name of Device:
Model HY5000 Thermassage Energy Product

Common or Usual Name
Massage Therapy Table

Classification Name
Multi-Functional Physical Therapy Table

K032449/S1

Predicate Devices

1. LSI International's Quantum Intersegmental Roller Traction Table (K002390)

2. Williams Healthcare's Combi 2.5 Intersegemental Traction Table (K933443)

Intended Use

The intended use of the Migun Model HY5000 Thermassage Energy Product is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the device includes infrared lamps which emit energy in the infrared spectrum, and provide topical heating for the purpose of elevating tissue for the temporary relief of minor muscle and joint pain, and stiffness.

Device Description

The Migun Model HY5000 Thermassage Energy Product is an electrically powered, motorized, multifunctional physical therapy table. It's intended function and use is to provide patients with muscle relaxation therapy by delivering heat and soothing massage.

The massage function is delivered by way of two (2) independent carriages, which are mounted under a pad of the table torso section. The heat function is delivered by use of ten (10) infrared lights, which are mounted directly to the traversing carriages. Each carriage has five (5) infrared lights. During use, these carriages traverse from lower torso to upper torso and apply light pressure as well as heat to the supine user.

PERFORMANCE DATA

The Model HY5000 Thermassage Energy Product has been tested to and meets the requirements of the following standards.

1. Underwriters Laboratories (U.L) Standard UL 2601 2nd Edition (1997) "Medical Electrical Equipment, Part 1: General Requirements for Safety 2nd Edition Including Amendments 1 and 2"

2. CAN/CSA C22.2 No. 601.1-M90, "Medical Equipment-Part 1: General Requirements for Safety, including C22.2 No. 601.1S1-94. IEC 601.1, Amendment, 1:1991 Supplement No. 1-94 to CAN/CSA 22.2 No. 601.1-M90"

3. EN 60601-1 (1990), "Medical Electrical Equipment Part 1, General Requirements for Safety including Amendments A1 and A2'

4. IEC 60601-1, 2nd Edition (1998) "Medical Equipment – General requirements for Safety + A1:91 and A2:95."

5. IEC 60601-2-38 1ST Edition (1996) "Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Electrically Operated Beds."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

Migun Medical Instrument Co., Ltd.
C/o Mr. Edward A. Kroll
Spectre Solutions, Inc.
5905 Fawn Lane
Cleveland, Ohio 44141

Re: K032449
Trade/Device Name: Migun HY5000 Thermassage Energy Product
Regulation Number: 21 CFR 890.5880, 21 CFR 890.5500
Regulation Name: Multi-function physical therapy table, Infrared lamp
Regulatory Class: II
Product Code: JFB, ILY
Dated: September 24, 2003
Received: September 26, 2003

Dear Mr. Kroll:

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.

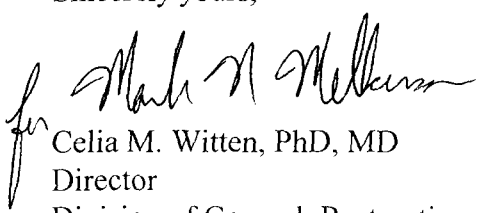
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-1308. 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,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): *TBD*

Device Name: Migun HY5000 Thermassage Energy Product

Indications For Use:

- The intended use of the Migun Model HY5000 Thermassage Energy Product is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the infrared lamps provide topical heating for;
  - temporary relief of minor muscle and joint pain, and stiffness
  - the temporary relief of minor joint pain associated with arthritis
  - the temporary increase in local circulation where applied
  - relaxation of muscles

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

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

(510(k) Number K032449