K053041

510(k) Summary of Safety and Effectiveness for the MED Sculpt Computerized Body Massager and M-Sonic Ultrasound Diathermy

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

AUG 0 2 2006

1. General Information

Submitter: General Project, S.r.l.
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Italy

Contact Person: Maureen O'Connell
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North Reading, MA 01864
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Summary Preparation Date: August 1, 2006

2. Names

Device Name: MED Sculpt Computerized Body Massager and M-Sonic Ultrasound Diathermy

Classification Name: Therapeutic Massager and Ultrasonic Diathermy
Product Code: IMI, ISA

3. Predicate Devices

The MED Sculpt Computerized Body Massager and M-Sonic Ultrasound Diathermy is substantially equivalent to the Dermosonic, manufactured by Sybaritic, Inc. (K024307).

4. Device Description

The MED SCULPT Computerized Body Massager and M-Sonic Ultrasound Diathermy system has massage and ultrasound diathermy components. The massage portion of the device uses a specially designed membrane, made up of elastomeric material. This membrane, fastened onto the handpiece, moves in an alternate way due to changeable depression created by a vacuum pump; such movement is due to the opening and closing of two electronically controlled electrovalves. The unit also includes an ultrasonic handpiece that can be used to perform ultrasound diathermy. Ultrasound is a particular form of mechanical energy which leads to an increase in the molecular vibration of the tissue resulting in heat generation and according to this principle the ultrasonic

handpiece of the unit, using an ultrasound wave at the fixed frequency of 3 MHz, produces thermal changes in the areas of the body where it is applied.

5. Indications for Use

The MED Sculpt Computerized Body Massager and M-Sonic Ultrasound Diathermy is indicated for:

a. Therapeutic Massager:
   i. Provides temporary relief of minor muscle aches and pains
   ii. Relieves muscle spasms
   iii. Temporarily improves local blood circulation
   iv. Temporarily reduces the appearance of cellulite

b. Ultrasonic Diathermy:
   i. Relief of pain
   ii. Muscle spasms
   iii. Joint contractures
   iv. NOT for the treatment of malignancies

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2006

General Project S.r.l.
C/O Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K053041
Trade/Device Name: MED Sculpt Computerized Body Massage and M-Sonic Ultrasound Diathermy
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI and ISA
Dated: June 28, 2006
Received: June 29, 2006

Dear Ms. O'Connell:

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.

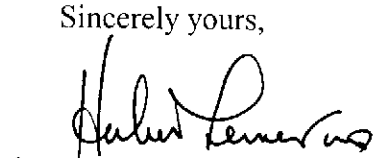
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



for Mark N. Melkerson, M.S.
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): K053041

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053041