K091615

MAY - 6 2010

510(k) Summary
For the General Project MC1

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.

1. General Information

Submitter:	General Project, S.r.l. Via della Gora 13/19-15/19 50025 Montespertoli, Florence Italy
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Tel: 978-207-1245 Fax: 978-824-2541
Summary Preparation Date:	April 26, 2010

2. Names

Trade Name:	MC1
Common Name:	Ultrasound and Massager
Classification Name:	Therapeutic Massager Diathermy, Ultrasonic, For Use in Applying Therapeutic Deep heat. Product Codes: ISA (21 CFR 890.5660), IMI (21 CFR 890.5300)

3. Legally Marketed Predicate Devices

The MC1 is substantially equivalent to the following devices: MED Sculpt, manufactured by General Project (K053041), Dermosonic, manufactured by Sybaritic, Inc. (K024307), Forte CPS 400 Combo (K982830), manufactured by Chattanooga Group, Inc. and Omnisound 3000 (K883893), manufactured by Physio Technology, Inc.

4. Device Description

The MC1 is a computerized body massager and ultrasound diathermy system. The MC1 is supplied with two handpieces: one ultrasonic handpiece with two 1 MHz transducers mounted on it and one handpiece for computerized body massage.

5. Intended Use

The MC1 is indicated for:

a) Therapeutic Massager:
   1. Provides temporary relief of minor muscle aches and pains
   2. Relieves muscle spasms
   3. Temporarily improves blood circulation
   4. Temporarily reduces the appearance of cellulite

b) Ultrasonic Diathermy:
   1. Relief of pain
   2. Muscle spasms
   3. Joint contractures
   4. NOT for the treatment of malignancies

6. Substantial Equivalence

The MC1 is substantially equivalent to the identified predicate devices. The MC1 has the same indications for use as the General Project MED Sculpt and the Sybaritic Dermosonic. Regarding technological characteristics, the MC1 includes both massage and ultrasound diathermy handpieces as do the General Project MED Sculpt and the Sybaritic Dermosonic. The Chattanooga Group, Inc. Forte CPS 400 Combo and the Physio Technology, Inc. Omnisound 3000 are ultrasound based devices only. Differences between the MC1 and the identified predicate devices were evaluated in performance testing and the MC1 was found to be substantially equivalent to the identified predicate devices.

7. Performance Data

The MC1 was tested and found to conform with IEC 60601-1 for electrical safety, IEC 60601-1-2 for electromagnetic compatibility and IEC 60601-2-5 for electrical safety in ultrasonic physiotherapy equipment. The MED Sculpt was found to conform with these same electrical safety standards. Performance data was presented which showed that the MC1 performed similarly to the previously cleared MED Sculpt in terms of tissue heating. Specifically, testing showed that the MC1 increases tissue temperature as required for ultrasonic diathermy. The two 1 MHz ultrasound transducers can be considered equivalent to the MED Sculpt in terms of heating tissue temperature to at least 40° C. These results are similar to those reported for the MED Sculpt.

8. Conclusion

The MC1 is substantially equivalent to the identified predicate devices in terms of indications for use, electrical safety testing and performance testing which indicated that the MC1 and the MED Sculpt were substantially equivalent in terms of tissue heating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

General Project, S.r.l
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

MAY - 6 2010

Re: K091615
Trade/Device Name: MC1
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Regulatory Class: II
Product Code: IMI, ISA
Dated: April 26, 2010
Received: April 27, 2010

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. 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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: MC1

The MC1 is indicated for:

a) Therapeutic Massager:
   1. Provides temporary relief of minor muscle aches and pains;
   2. Relieves muscle spasms,
   3. Temporarily improves local blood circulation;
   4. Temporarily reduces the appearance of cellulite.

b) Ultrasonic Diathermy:
   1. Relief of pain;
   2. Muscle spasms;
   3. Joint contractures;
   4. NOT for the treatment of malignancies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X

Prescription Use (Per 21 CFR 801.109)	OR	Over The Counter Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical
and Restorative Devices

510(k) Number K091615