



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

August 16, 2016

General Project S.R.L.
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, Massachusetts 01864

Re: K161502
Trade/Device Name: MC1 Plus
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI, ISA
Dated: July 19, 2016
Received: July 20, 2016

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161502

Device Name

MC1 Plus

Indications for Use (Describe)

The MC1 Plus 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY K161502
As required by Section 807.82(c)

- 1. Submitter:** [807.92 (a)(1)]
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- 2. Contact Person:** [807.92 (a)(1)]
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North Reading, MA 01864
tel: (978) 207-1245

- 3. Date Summary Prepared:** [807.92 (a)(1)]
July 19, 2016

- 4. Device Names:** [807.92 (a)(2)]
Proprietary MC1 Plus
Common Diathermy, Ultrasonic, For Use in Applying Therapeutic Deep Heat and Therapeutic Massager

Classification Name	Prod. Code	CFR
Class II, Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat	IMI	890.5300
Class I, Massager, Therapeutic, Electric	ISA	890.5660

- 5. Reason for Submission of Special 510(k):**
Change of User Interface and power output level to comply with IEC 60601-2-5 3rd ed. standard

- 6. Modification to Existing Device (Predicate):** [807.92 (a)(3)]
K091615 MC1 computerized body massager and ultrasound diathermy device (Cleared May 6, 2010)

- 7. Reason for Device Modification:** [807.92 (d)]
To better the usability of the device using a wider display and a software with improved graphic. To provide a better maintenance, a more robust software solution and an easier scalability. To comply the user interface to the status of art, in particular to comply standard IEC 60601-2-5 3rd ed.

- 8. Device Description:** [807.92 (a)(4)+(6)]
MC1 Plus is a computerized body massager and ultrasound diathermy system. The MC1 Plus is supplied with two handpieces: one ultrasonic handpiece with two 1 MHz transducers mounted on it and one handpiece for computerized body massager.

9. Intended Use: [807.92 (a)(5)]

The MC1 Plus 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.

10. Industry Standards: [807.92 (d)]

General Project declares the conformance to the following standards:

AAMI/ANSI ES60601-1, Medical Electrical Equipment-Part 1: General Requirements for Safety, 3rd ed

IEC 60601-1-2, General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests, 3rd ed

IEC 62304, Medical Device Software - Software Life Cycle Processes

IEC 60601-2-5, Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment, 3rd ed

11. Information Bearing on the Safety and Effectiveness

The General Project MC1 Plus has the same intended use as MC1 cleared device (K091615). There is no change in materials, classification or labeling. There is no change in the system of control of the device. There are no modifications that have the potential to alter the fundamental scientific technology. The only changes are in the Human Interface and the level of ultrasonic power output. These changes do not affect the safety or effectiveness of the device. Rather, the human interface changes improve the usability of the device using a wider display and a software with a improved graphic and furthermore provide a better maintenance, a more robust software solution and an easier scalability. The maximum ultrasonic power output (now 15 W with max intensity level of 3 W/cm², before 21 W with max intensity level of 7 W/cm²) has changed to comply IEC 60601-2-5 3rd ed. There are no additional characteristics known that should adversely affect the safety and effectiveness of this device. The results of design validation raise no new issues of safety and effectiveness.

12. COMPARISON of DESIGN, SAFETY and EFFECTIVENESS

Parameters	Subject device K161502	Predicate device K091615	Rationale
Manufacturer	General Project	General Project	Same

IFU	<p>a. Therapeutic massager</p> <ol style="list-style-type: none"> 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 <p>b) ultrasonic diathermy</p> <ol style="list-style-type: none"> 1. Relief of pain 2. Muscle spasms 3. Joint contractures 4. Not for the treatment of malignancies 	<p>a. Therapeutic massager</p> <ol style="list-style-type: none"> 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 <p>b) ultrasonic diathermy</p> <ol style="list-style-type: none"> 1. Relief of pain 2. Muscle spasms 3. Joint contractures 4. Not for the treatment of malignancies 	Same
Type	Ultrasound and vacuum pressure massage	Ultrasound and vacuum pressure massage	Same
Product code	IMI, ISA	IMI, ISA	Same
Preselected programs	Ultrasound handpiece: 24 programs Zonal massage handpiece: 6 programs	Ultrasound handpiece: 24 programs Zonal massage handpiece: 6 programs	Same
Protection grade	IP 20	IP 20	Same
Operating conditions	<p>Temperature: 15 - 40 °C (59 - 104 °F)</p> <p>RH 65% maximum</p> <p>Max operative altitude: 2000 m (6500 ft) above sea level</p>	<p>Temperature: 15 - 40 °C (59 - 104 °F)</p> <p>RH 65% maximum</p> <p>Max operative altitude: 2000 m (6500 ft) above sea level</p>	Same
Storage environmental conditions	<p>Temperature: 0 - 45 °C (32 - 113°F)</p> <p>RH 80% max</p>	<p>Temperature: 0 - 45 °C (32 - 113 °F)</p> <p>RH 80% max</p>	Same
Dimensions	700 x 675 x h1740 mm (28" x 26.6" x 68.5") with articulated arm.	<p>560 x 650 x h380 mm (22"x25.6"x15") without trolley</p> <p>560 x 650 x h1200 mm (22"x25.6"x47.2") with trolley</p>	Different, but does not adversely impact safety and effectiveness of the subject device
Weight	<p>76 kg (167 lbs) with short arm</p> <p>78 kg (172 lbs) with articulated arm</p>	55 kg (121.25 lbs) with trolley	Different, but does not adversely impact safety and effectiveness of the subject device
Material	Baydur, Aluminium, SEBS/SEPS Thermoplastic Polymers	Baydur, Aluminium, SEBS/SEPS Thermoplastic Polymers	Same
Zonal massage handpiece			
a. Max attainable vacuum	-55kPa	-55kPa	Same
b. Suction time	200 – 300ms depending on the selected program	200 – 300ms depending on the selected program	Same
c. Relax time	500 – 1500ms depending on the selected program	500 – 1500ms depending on the selected program	Same
d. Treatment time	4 – 8 mins depending on the selected program	4 – 8 mins depending on the selected program	Same
e. Dimensions of the	42 mm	42 mm	Same

massage head			
Ultrasound handpiece			
a. Applicator size	double applicator diameter 42 mm each applicator area 13.8 cm ² each total active surface 27.7cm ²	double applicator diameter 42 mm each applicator area 13.8 cm ² each total active surface 27.7cm ²	Same
b. Crystal material	PZT	PZT	Same
c. Output mode	Continuous or pulsed (sinusoidal wave mode)	Continuous or pulsed (sinusoidal wave mode)	Same
d. Ultrasound frequency	1 MHz (± 20%)	1 MHz (+ 20%)	Same
e. Modulated frequency	20 – 60 kHz ± 10%	20 – 60 kHz ± 10%	Same
f. Ultrasound intensity	0.5 – 3W/cm ² for each transmitter in continuous and modulated emission mode	1 – 7 W/cm ² for each transmitter in continuous emission mode 1 – 5 W/cm ² for each transmitter in modulated emission mode	Different but subject device has reduced intensity which does not adversely impact safety and effectiveness of the subject device and complies with IEC 60601-2-5
g. BNR (Beam non-uniformity ratio)	≤ 4:1	≤ 4:1	Same
h. ERA (Effective Radiating Area)	4.9 cm ²	3 cm ²	Different but does not adversely impact safety and effectiveness of the subject device and complies with IEC 60601-2-5
i. Duty cycle	N/A	N/A	N/A
j. Pulse duration	50 – 8.33 μs	50 – 8.33 μs	Same
k. Pulse frequency	20 – 60 kHz	20 – 60 kHz	Same
l. Treatment time	5 – 8 mins depending on selection, max activation time 30 mins	5 – 8 mins depending on selection, max activation time 30 mins	Same
m. Temporal max power (if pulsed) (W)	14.70	23.91 ± 20%	Different but subject device has reduced temporal max power (when pulsed) which does not adversely impact safety and effectiveness of the subject device and complies with IEC 60601-2-5
n. Temporal max power (if continuous) (W)	14.60	20.55 ± 20%	Different but subject device has reduced temporal max power (when continuous) which does not adversely impact safety and effectiveness of the subject device and complies with IEC 60601-2-5
o. Instantaneous peak power	N/A	N/A	MC1 Plus ultrasound emission modality makes the instantaneous peak power value meaningless as it is

			equal to the average value and complies with IEC 60601-2-5
p. Temporal max effective intensity (W/cm ²)	3.00	7.97	The maximum emitted power has been changed from 7 W/cm ² to 3 W/cm ² and complies with IEC 60601-2-5
q. Temporal avg effective intensity (W/cm ²)	2.98 without modulation	6.85 without modulation	The average emitted power has been changed from 7 W/cm ² to 3 W/cm ² and complies with IEC 60601-2-5
r. Max suction pressure	N/A	N/A	These values are no longer meaningful since the machine design had been modified eliminating the vacuum suction from the ultrasound handpiece
s. Suction time	N/A	N/A	
t. Relax time	N/A	N/A	
Leakage current			
a. Ground leakage current Normal Condition (NC) (<0.500 mA)	0.085	0.065	Similar
b. Ground leakage current Single Fault Condition (SFC) (<1.0 mA)	0.107	0.102	Similar
c. Patient leakage current NC DC (<0.01 mA)	<0.001	<0.001	Same
d. Patient leakage current NC AC (<0.10 mA)	<0.01	<0.001	Patient leakage current of subject device is 10x higher but still under the acceptable range as per IEC 60601-1 and does not adversely affect the safety and effectiveness of the subject device
e. Patient leakage current SFC DC (<0.05 mA)	<0.001	<0.001	Same
f. Patient leakage current SFC AC (<0.50 mA)	<0.01	<0.001	Patient leakage current of subject device is 10x higher but still under the acceptable range as per IEC 60601-1 and does not adversely affect the safety and effectiveness of the subject device

13. Substantial Equivalence

The MC1 Plus is substantially equivalent to the MC1 cleared in K091615. The MC1 Plus has the same indications for use as the General Project MC1. Regarding technological characteristics, the MC1 Plus includes both massage and ultrasound

diathermy handpieces as do the General Project MC1. The maximum ultrasound intensity has been reduced from 7 W/cm² to 3 W/cm² to comply standard IEC 60601-2-5 3rd ed; the maximum ultrasonic power output is 15 W, while in MC1 device was 21 W, the ERA is 4.9 cm² instead of 3 cm².

Differences between the MC1 Plus and the MC1 device were evaluated in performance and effectiveness testing and the MC1 Plus was found to be substantially equivalent to the MC1 device.

14. Performance Data

The MC1 Plus was tested and found to conform with AAMI/ANSI ES60601-1 for electrical safety, IEC 60601-1-2 for electromagnetic compatibility and IEC 60601-2-5 for electrical safety in ultrasonic physiotherapy equipment. The MC1 was found to conform with these same electrical safety standards. Performance data was presented which showed that the MC1 Plus performed similarly to the previously cleared MC1 in terms of tissue heating. Specifically, testing showed that the MC1 Plus increases tissue temperature as required for ultrasonic diathermy. The two 1 MHz ultrasound transducers can be considered equivalent to the MC1 in terms of heating tissue temperature to at least 40° C. These results are similar to those reported for the MC1.

15. Conclusion

The MC1 Plus is substantially equivalent to the MC1 device in terms of indications for use, electrical safety testing and performance testing which indicated that the MC1 Plus and the MC1 were substantially equivalent in terms of tissue heating.