K093259

**510(k) Summary**

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| Submitted by: | ARP Manufacturing<br>7200 E. Dry Creek Road, Suite G-102<br>Centennial, CO 80112 |
| Contact Person | Lewis Ward<br>L.W. Ward and Associates, Inc.<br>4655 Kirkwood Court<br>Boulder, CO 80301 |
| Date Prepared: | September 3, 2009 |
| Product: | Trade Name: ARP Rx100<br>Common Name: Powered Muscle Stimulator |
| Classification Name: | Stimulator, Muscle, Powered, 890.5850, Product Code IPF |
| Intended Use: | The ARP Rx100 is intended for the following applications:<br>• Relaxation of muscle spasms<br>• Prevention or retardation of disease atrophy<br>• Increasing local blood circulation<br>• Muscle re-education<br>• Maintaining or increasing range of motion |
| Technological Characteristics: | The system consists of a table top electrical generator producing optimal continuous or interrupted electrical impulses through patient electrodes. Control parameters are software controlled through an LCD touch screen. |
| Substantial Equivalence: | The Rx100 Powered Muscle Stimulator is substantially equivalent to the TheraStim Muscle Stimulator, K893851. The modes, frequency, output, and indications for use are substantially equivalent. |
| Test Data: | The ARP Rx100 has been demonstrated safe by testing to IEC 60601-2-10. The Device compared to the Predicate is substantially equivalent, safe and as effective. |

DEC 17 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

ARP Manufacturing, Inc.
% Regulatory Technology Services LLC
Mr. Mark Job
1394 25th Street NW
Buffalo, MN 55313

DEC 17 2009

Re: K093259
Trade/Device Name: ARP Rx100
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator.
Regulatory Class: Class II
Product Code: IPF
Dated: November 28, 2009
Received: December 2, 2009

Dear Mr. Job:

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 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: ARP Rx100

Indications for Use:

The ARP Rx100 is indicated for the following applications:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

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

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