510(k) Summary

Submitted by: ARP Manufacturing
7200 E. Dry Creek Road, Suite g-102
Centennial, CO 80112

AUG 10 2010

Contact Person Lewis Ward
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301

K093999

Date Prepared: 5-27-10

Product: Trade Name: ARP POV Sport
Common Name: Powered Muscle Stimulator, OTC

Classification Name: Stimulator, Muscle, Powered, 890.5850, Product Code NGX

Intended Use: The ARP POV Sport is intended for the following:

The ARP POV Sport is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

The ARP POV Sport is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The ARP POV Sport is not designed for use on injured or ailing muscles and its use on such muscles is contraindicated.

The POV Sport's electrical impulses allow triggering action potential on motoneurones of motornerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that the POV Sport can impose on the stimulated muscles are able to improve or facilitate muscle performance.

The ARP POV Sport is considered a technique of muscle training.

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 POV Sport Powered Muscle Stimulator is substantially equivalent to the Compex Sport K011880, the TheraStim Muscle Stimulator K893851, and Endurance Therapeutics Model T1040 K060846. The modes, frequency, output, and indications for use are substantially equivalent.
Test Data:	The ARP POV Sport has been demonstrated safe by testing to IEC 60601-2-10, IEC 60601-1-1:2000, IEC 60601-1-2:2008, and IEC 60601-1-4:2000. The device compared to the predicate is substantially equivalent, safe and as effective.

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

ARP Manufacturing, Inc.
% L.W. Ward and Associates, Inc.
Mr. Lewis Ward
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K093999
Trade/Device Name: ARP POV Sport
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: August 4, 2010
Received: August 6, 2010

AUG 10 2010

Dear Mr. Ward:

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

K093999

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: ARP POV Sport

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Indications for Use:

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The various types of muscle work that the POV Sport can impose on the stimulated muscles are able to improve or facilitate muscle performance.

The ARP POV Sport is considered a technique of muscle training.

Prescription Use _____ 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)

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

510(k) Number K093999