AdRem TECHNOLOGY

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K072252

SUMMARY OF SAFETY AND EFFECTIVENESS

1-0 ADMINISTRATIVE INFORMATON

1-1 SPONSOR IDENTIFICATION (510(k) OWNER)

AdRem Technology
162 rue du Fauburg St. Honore
PARIS
Postal Code 75012
France
Mr. Olivier Huon, Chief Executive Officer
Mr. Thierry Tavidian, President
Telephone 011-331-4260 0022
Fax 011-331-4260 0063
tt@adremtechnology.com
oh@adremtechnology.com

JAN 30 2008

1-2 ESTABLISHMENT REGISTRATION NUMBER: Pending

1-3 OFFICIAL CONTACT PERSON / OFFICIAL CORRESPONDENT / AGENT

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854
estrin@yourFDAconsultant.com
Tel: (301) 279 -2899
Fax: (301) 294-0126

1-4 DATE OF PREPARATION OF THIS SUMMARY

August 9 2007

1-5 PROPRIETARY (TRADE) NAME

VEINOPLUS® Neuromuscular Stimulator

1-6 COMMON NAME

Muscle Stimulator, Neuromuscular Stimulator, NMS, EMS (when used in Mode 1); Nerve Stimulator, TENS, Pain Control Stimulator (when used in Mode 2)

v: v012

1-7 CLASSIFICATION NAME
Powered muscle stimulator; Stimulator, nerve, transcutaneous, for pain relief

1-8 REGULATION NUMBERS: 21 CFR 890.5850; 21 CFR 882.5890

1-9 PROPOSED REGULATORY CLASS: Class 2

1-10 DEVICE PRODUCT CODES: 89 IPF and GZJ

1-11 MEDICAL SPECIALTIES: Physical Medicine; Neurology

2-0 DESCRIPTION OF DEVICE

The **VEINOPLUS® Neuromuscular Stimulator** is a traditional battery powered muscle stimulator and it is combined with the TENS stimulator. It is a single channel device with its Operating Modes stored in the internal memory. The **VEINOPLUS®** provides two separate and switchable independent Operating Modes of stimulation.

3-0 INDICATIONS FOR USE:

The VEINOPLUS® Neuromuscular Stimulator is indicated for the following:

In the Primary Mode of Action (PMOA) when the Operating Mode number 1 for muscle stimulation is activated, the Indications for Use are:

- Relaxation of muscle spasms.
- Prevention or retardation of muscle disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion.

In the other Mode of Action (MOA) when the Operating Mode number 2 for Transcutaneous Electrical Nerve Stimulation (TENS) stimulation is activated, the Indications for Use are:

- Providing symptomatic pain relief for chronic, acute or post operative pain.

4-0 PREDICATE DEVICES

K022175 Trade/Device Name: VALMED P4-PHYSIO.
Regulation Number: 21 CFR 890.5850

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Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
The equivalence is claimed only for the Operational Mode number 1 of the **VEINOPLUS®**

K040253 Trade/Device Name: EASYMED TN-28C T.E.N.S. Unit
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
The equivalence is claimed only for the Operational Mode number 2 of the **VEINOPLUS®**

5-0 SUBSTANTIAL EQUIVALENCE

The VEINOPLUS® Neuromuscular Stimulator is substantially equivalent to the VALMED P4-PHYSIO (K022175) in mode number 1 (neuromuscular stimulation) and to the EASYMED TN-28C T.E.N.S. Unit (K040253) in mode number 2 (TENS stimulation). Both **VEINOPLUS®**, the VALMED P4-PHYSIO the EASYMED TN-28C T.E.N.S. Unit comply with the Voluntary Standards: ANSI/AAMI NS4-1985, IEC 60601-2-10, PART 2 and MDD 93/42/EEC and to 21 CFR § 898.

6.0. CONCLUSION

The **AdRem VEINOPLUS® Neuromuscular Stimulator** meets appropriate standards and raises no safety/efficiency issues or claims that differ from the predicate device cited.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2008

AdRem Technology SARL
% Estrin Consulting Group, Inc.
Dr. Norman Estrin
9109 Copenhaven Drive
Potomac, MD 20854

Re: K072252
Trade/Device Name: Veinoplus Neuromuscular Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: December 11, 2007
Received: December 21, 2007

Dear Dr. Estrin:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): _____

Device Trade/Proprietary Name: VEINOPLUS® Neuromuscular Stimulator

Indications for Use:

The VEINOPLUS® Neuromuscular Stimulator is indicated for the following:

In the Primary Mode of Action (PMOA) when the Operating Mode number 1 for muscle stimulation is activated, the Indications for Use are:

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- Providing symptomatic pain relief for chronic, acute or post operative pain.

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December 13, 2003) _____

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K072257