510(K) SUMMARY

SmartStep System

510(k) Number K 0 2 3 1 6 1

DEC 1 0 2002

Applicant's Name:

Andante Medical Devices Ltd.
15 Yehoshua Hatsoref Street
Beer-Sheva 84106, Israel
Tel.: 972-8-6239043
Fax: 972-8-6231246

Contact Person:

Orly Maor
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
Fax: 972-9-7718131

Date Prepared:

September 2002

Trade Name:

SmartStep System

Classification Name:

DEVICE, WARNING, OVERLOAD, EXTERNAL LIMB, POWERED

Classification:

The FDA has classified Enteroscopes as class II devices (product code IRN, Regulation No. 890.5575) and they are reviewed by the Physical Medicine Panel.

Predicate Device:

- Ped Alert Plenet manufactured by Planet Products Corp USA (former Orbitec Technologies Corp.) cleared under K950656.
- ForceGuard manufactured by Impact Monitors, Inc. USA cleared under K955034.
- AccuTread™ System manufactured by Chattanooga Group Inc. cleared under K991313.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the SmartStep System complies with the voluntary standards such as IEC 60601-1, IEC 60601-2, IEC 60601-1-4, EN-1441.

Intended Use:

The SmartStep System is intended to sense the amount of weight applied to the plantar surface of the foot during rehabilitation. The device alerts the user and/or therapist with alarm when the weight exceeded the pre-selected value. Furthermore, the SmartStep System is intended to be used in any situation in which therapist and/or patient would benefit from objectively assessing the amount of weight that is being applied to a lower limb.

Device Description:

The SmartStep System is a biofeedback system for gait training and re-education. The device is a tool to assist clinicians accurately assess patients who are undergoing weight bearing restrictions and gait therapy training.

The SmartStep is used to measure the amount of weight being applied to an affected limb, to teach and promote specific weight bearing skills, and to test patient's ability to maintain a weight bearing rang. A patient's weight bearing status is important to know because it is an indicator of overall progress, and with certain conditions, under-weight bearing or over-weight bearing can lead to complication in the rehabilitation process.

The SmartStep system is to be used under the supervision of physician or licensed health care provider such as physiotherapist.

The SmartStep system is comprised of three sub elements:

Flexible Foot force insole that is placed on the inside of a shoe worn by the patient over a sock.
Central Processing Unit (CPU)- the unit is connected to computer software.
Computer software that acts as a patient medical record and patient assessment tool.

Substantial Equivalence:

Based on validations and performance testing results, Andante Medical Devices Ltd. believes that the SmartStep System is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2002

Mr. Orly Maor
Push-Med Ltd.
for Andante Medical Devices Ltd.
117, Ahuza Street
Ra'ananna 43373, ISRAEL

Re: K023161
Trade/Device Name: Andante SmartStep System
Regulation Number: 21 CFR 890.5575
Regulation Name: Powered External Limb Overload Warning Device
Regulatory Class: II
Product Code: IRN
Dated: September 18, 2002
Received: September 23, 2002

Dear Mr. Maor:

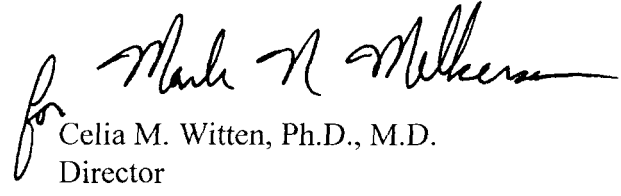
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639.
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023161

Device Name:

SmartStep System

Indications for Use:

The SmartStep System is intended to sense the amount of weight applied to the plantar surface of the foot during rehabilitation. The device alerts the user and/or therapist with alarm when the weight exceeded the pre-selected value. Furthermore, the SmartStep System is intended to be used in any situation in which therapist and/or patient would benefit from objectively assessing the amount of weight that is being applied to a lower limb.

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

510(k) Number _____

Prescription Use _____ OR Over the Counter Use _____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023161