MAY 2 4 2013

510(k) SUMMARY

1. Contact Information

Submitter's name: AMES Technology, Inc.
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Portland, OR 97225

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Date summary prepared: May 17, 2013

2. Device names:

Proprietary name	Common name	Classification names
AMES Therapy Device	Electromechanical physical therapy device	Isokinetic Testing & Evaluation Device Therapeutic Vibrator

Device Classification:

Classification Name	Product Code	21 CFR citation	Class	Panel
Isokinetic Testing & Evaluation Device	IKK	890.1925	II	Physical Medicine
Therapeutic Vibrator	IRO	890.5975	I	Physical Medicine

3. Predicate Devices:

The AMES Therapy Device is a combination of the intended use, functions, and features of the following currently marketed physical therapy devices:

510(k) Number	Product Code, Class	Trade Name	Manufacturer
K951770 (now 510(k)-exempt)	IKK Class II	System 4	Biodex Medical Systems, Inc.
N/A (510(k)-exempt)	IRO Class I	Vibracussor	Innovative Machinery Packaging and Converting, Inc.

4. Device Description:

The AMES Therapy Device is an electromechanical physical therapy device that combines 3 motion assemblies (one for the ankle, one for the wrist, and one for the thumb-and-fingers), 5 therapeutic vibrators, and a visual feedback unit, all contained in one device. The patient is seated in a separate conventional chair or wheelchair so that the appropriate limb can be attached to the AMES Therapy Device for therapy.

The AMES Therapy Device includes assisted movement to the limb being treated and applies simultaneous vibration to the antagonist muscle. The device provides visual feedback to the patient to indicate whether he/she is producing the requisite force (torque) in assisting the device's motion and encourages the patient to keep working the agonist muscle. The feedback also includes a force (torque) "target," set to a level by the therapist that the patient can achieve repeatedly during therapy without becoming too fatigued, but that is also moderately challenging. The torque produced by the patient is indicated on the video touch screen.

Testing and reporting on the patient's therapy and functional status can be performed at each therapy session prior to or following administration of therapy. Data for each session include therapy delivery (date, duration, performance) and test results. Two tests are carried out during the treatment session to measure: 1) active range-of-motion, and 2) strength. These test scores permit the therapist: (i) to determine each patient's baseline status at the time that the patient first receives the AMES therapy, and (ii) to monitor changes in rehabilitation status during the course of the patient's therapy. This testing enables therapists to modify the treatment regimen in response to observed improvements and to determine when the patient is no longer benefitting from the therapy.

The AMES Therapy Device is non-invasive and there is no electrical stimulation involved in the device, nor any recording of bioelectric potentials. No heat is applied by the AMES Therapy Device.

5. Intended Use/Indications for Use:

The AMES Therapy Device is a rehabilitative exercise therapy device that uses assisted movement to measure, evaluate, exercise, re-educate and strengthen muscles, and to increase joint range of motion. It also uses muscle vibration for muscle relaxation.

6. Comparison with the Predicate Devices:

Because the AMES Therapy Device combines the functions and characteristics of different physical therapy devices, multiple predicate devices are presented. Like the System 4 device, the AMES Device is intended to exercise, measure, evaluate and increase the strength of muscles and increase the Range of Motion (ROM) of joints. Like the Vibracussor device, the AMES Device is intended to relax muscles using vibration. The AMES Therapy Device uses isokinetic principles like the System 4 device to deliver therapy, and uses vibration like the Vibracussor device to deliver therapy to relax muscles. Based on these comparisons, the AMES Therapy Device is substantially equivalent to the predicate devices in intended use, indications for use, and device function and features.

7. Non-Clinical Testing:

Testing has been conducted to UL 60601-1 Standard for Safety for Medical Electrical Equipment, Part 1: General Requirements for Safety and IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Tests.

Biocompatibility testing for patient-contacting materials is included that demonstrates that the patient-contacting materials are not irritating, sensitizing, or cytotoxic.

Design verification testing was performed on fully functional AMES Therapy Devices to demonstrate that the AMES device performed as designed and met its specifications.

8. Clinical Testing:

Safety data from clinical evaluations of the AMES Therapy Device were used to evaluate the safety of the device with respect to skin integrity.

9. Conclusions:

Non-clinical testing showed that the AMES device performs as designed. Based on the information presented in this submission, we believe that the AMES Therapy Device is substantially equivalent to the predicate devices in intended use, indications for use, and device function and features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 24, 2013

AMES Technology, Inc.
C/O Ms. Sheila Ramerman, RAC
SJR Associates
927 Thorne Drive
Eugene, Oregon 97402

Re: K123746
Trade Name: AMES Therapy Device
Regulation Number: 21 CFR 890.1925
Regulation Name: Isokinetic Testing and Evaluation Device
Regulatory Class: Class II
Product Code: IKK, IRO
Dated: April 25, 2013
Received: April 26, 2013

Dear Ms. Ramerman:

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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting 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): K123746

Device Name: AMES Therapy Device

Indications For Use:

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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)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123746