K062631

Premarket Notification 510(k) Summary

1 Submitter Information

1.3 Company Name and Address:

APR 12 2007

Myomo Incorporated
529 Main Street, Suite 205
Charlestown, MA 02129

1.4 Contact Name:

Kate Zebrose , Vice President, Product Development
Phone: 617-996-9058
Fax: 617-886-0333

1.5 Date Prepared: April 11, 2007

2 Name of Device

Trade Name: Myomo e100

Common Name: Active Elbow Brace

Classification Name:

890.1375, EMG-triggered powered exercise equipment OAL
890.5380, Powered Exercise Equipment, applicable product code BXB
890.3475, Limb Orthosis, applicable product code IOY

3 Substantial Equivalence Claimed to Predicate Devices

Kinetec 6080 CPM for Elbow, Class I
Biomove 3000, Class II - K042650, cleared January 27, 2005
Boston Digital Arm System, Class I

4 Device Description

The Myomo e100 is an electromechanically powered device intended to facilitate movement and increase range of motion for stroke patients. This device would be included as part of prescribed physical therapy to enable stroke patients to exercise that would otherwise be unable to independently do so. The Myomo e100 is an automatic strength amplifier using the detected electromyograph (EMG) as an indication of residual muscle strength. In the case of a patient who is unable to move his/her arm, the addition of strength amplification allows him/her to perform standard physical therapy exercises.

The Myomo e100 is available in left and right arm configurations. Foam pad inserts of various shapes are provided for fitting the brace for individual patients. Placement of the EMG sensors is configured for the individual patient allowing placement on either the tricep or bicep depending on the prescribed exercise. Optional adjustments for bicep and tricep gain are set and stored as part of the customization.

As pictured in Figure 1, adjustable straps are used to attach the brace to the arm. Once the brace is properly fitted to the arm the Myomo e100 is turned on using the "Control User Interface". The EMG signals are calibrated in the resting position and then the brace is ready for operation. The battery pack attaches to the "Control User Interface" and is not in contact with the patient.

The prescribing health care provider incorporates use of the Myomo e100 as part of a patient's physical therapy regimen. Progress can be monitored through the prescribed therapy using a goniometer, Fugl-Meyer testing, or other conventional evaluation techniques.

The Myomo e100 consists of three main elements:

4.1 Brace: provides support for the forearm during lift.

4.2 EMG Sensors: B & L Electrodes

4.3 Control User Interface: provides the signal processing function and the motor mechanism and controls for operation of the Myomo e100.

5 Intended Use

The Myomo e100 is indicated for use by stroke patients undergoing rehabilitation to facilitate the following:

- Stroke rehabilitation by muscle re-education
- Maintaining or increasing range of motion

6 Predicate Device Comparison of Indications for Use / Intended Use and Technical Characteristics

The comparison of the Myomo e100 was based on a review of the Design Control documentation for the device, relevant aspects of which are included in the company's 510(k) Premarket Notification, and information concerning the predicate devices that was available to the company via the FDA web site or those of the respective companies. The comparison considered technical characteristics and the indications for use / intended use. Neither bench, animal nor clinical testing were assessed.

7 Performance Data

7.1 Performance Standards (Section 514 Compliance): No performance standards applicable to this device under the following product codes have been adopted under Section 514 of the Food Drug and Cosmetic Act: 890.5380, Powered Exercise Equipment, and 890.3475, Limb Orthosis.

Title 21 CFR Part 898 Performance Standard for Electrode Lead is applicable to this device under the product code: 890.1375, Diagnostic Electromyography and is demonstrated by conformity to IEC 60601-1-1 as indicated below.

7.2 FDA Recognized Standards: The Myomo e100 conforms to the following.

7.2.1 Thermal, Electrical and Mechanical Safety: IEC 60601-1-1, Medical Electrical Equipment - Part 1: General Requirements for Safety 1: Collateral Standard: Safety Requirements for Medical Electrical Systems

7.2.2 Electromagnetic Compatibility: IEC 60601-1-2, Medical Electrical Equipment - Part 1: General Requirements for Safety 2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

7.2.3 Software

FDA's "Reviewer Guidance for the Content of Premarket Submission for Software Contained in Medical Devices", May 11, 2005

FDA's "Guidance for Off-The-Shelf Software Use in Medical Devices"

7.2.4 Risk Analysis: ISO 14971:2000, Application of risk management to medical devices

7.2.5 Biocompatibility: ISO 10993-1:2003, Biological evaluation of medical devices

7.3 Performance Testing: Design verification and design validation, e.g., bench testing was performed according to FDA's Design Control Requirements, Title 21 Code of Federal Regulations, Part 820.30.

8 Conclusion:

The information and data provided in this 510(k) Premarket Notification establish

that the Myomo e100 is substantially equivalent to the afore-mentioned predicate devices with respect to indications for use/intended use, and technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Myomo, Inc.
% Ms. Kate Zebrose
Vice President, Product Development
The Schrafft Center
529 Main Street, Suite 205
Boston, MA 02129

APR 12 2007

Re: K062631
Trade Name: Myomo e 100
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: II
Product Code: OAL
Dated: January 11, 2007
Received: January 12, 2007

Dear Ms. Zebrose:

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its 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

ODE Indications Statement

510(k) Number (if known): K062631

Device Name: Myomo e100

Indications for Use:

The Myomo e100 is indicated for use by stroke patients undergoing rehabilitation to facilitate the following:

- Stroke rehabilitation by muscle re-education
- Maintaining or increasing range of motion

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K062631

Prescription Use: X AND/OR Over-the-Counter Use:

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)