K080787

APR 17 2008

510(K) SUMMARY

Biomove 5000 System

510(k) Number K_____

A. Applicant's Name: Curatronic Ltd.
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B. Contact Person: Ofer Hornick M.D.
A. Stein – Regulatory Affairs Consulting
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Kfar Saba 44425
Israel
Tel. + 972-9-7670002
Fax. +972-9-7668534

C. Date Prepared: February 2008

D. Trade Name: Biomove 5000 System

E. Classification: **Name**: stimulator, muscle, powered
Product Code: IPF
Regulation No: 890.5850
Class: II
Panel: Physical Medicine

F. Predicate Devices: The Biomove 5000 is substantially equivalent to the Biomove 3000 device manufactured by the same company and cleared under number K042650 in terms of intended use, indications for use, technological characteristics, performance and user interface.

Both predicate devices are Class II medical devices.

A discussion of substantial equivalence is provided in this submission.

G. Device Description: The Biomove 5000 is a powered EMG triggered neuromuscular electrical stimulator device used as a training system for rehabilitation of paralyzed muscles, mainly after stroke.

The following accessories are supplied with the system: Patient Cable, re-usable electrodes (Biotrodes).

H. Intended Use / Indication for Use: The Biomove 5000 is indicated for:

1. Stroke Rehabilitation by Muscle Re-education
2. Prevention of retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Maintaining or increasing range of motion

I. Performance Standards: The Biomove 5000 complies with U.S. Federal Performance Standard as set forth in 21 CFR 898 for electrode lead wires and Patient Cables.

The device complies with the following recognized standards:

- IEC 60601-1(1988), including amendments #1(1991), #2(1995)
- IEC 60601-2-10 (1987)

The device complies with the Guidance Document for Powered Muscle Stimulator 510(k)s; Final (1999).

J. Technological Characteristics: The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the Biomove 5000 device are substantially equivalent to the predicate device cited above.

K. Substantial Equivalence: The Biomove 5000 System is substantially equivalent to its predicate device as cited above and raises no new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2008

Curatronic, Limited
% Ms. Ahava Stein
Regulatory Affairs Consulting
20 Hata'as Street
Kfar Saba 44425
Israel

Re: K080787
Trade/Device Name: Biomove 5000 system
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator.
Regulatory Class: Class II
Product Code: IPF
Dated: March 16, 2008
Received: March 20, 2008

Dear Ms. Stein:

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.
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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 STATEMENT

510(k) Number (if known): K080787

Device Name: Biomove 5000 System

Indications for Use:

The Biomove 5000 is indicated for:

1. Stroke Rehabilitation by Muscle Re-education
2. Prevention of retardation of disuse atrophy
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5. Maintaining or increasing range of motion

Prescription Use √ 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)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080787