JAN 2 7 2005

510(K) SUMMARY

Biomove 3000 System

510(k) Number K042650

A. Applicant's Name: Curatronic Ltd.
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B. Contact Person: Arava HaCohen, RAC
A. Stein – Regulatory Affairs Consulting
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C. Date Prepared: September 2004

D. Trade Name: Biomove 3000 System
(also known as the Curamove 3000 System outside of the US)

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

F. Predicate Devices: The Biomove 3000 is substantially equivalent to the NeuroMove NM900 device (Dan Med, Inc.) cleared under K012885 in terms of intended use, indications for use, technological characteristics, performance and user interface.

In addition, the Biomove 3000 is substantially equivalent to the AutoMove, Model AM800 (Danmeter A/S) cleared under K032955 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 Section 3 of this submission.

G. Device Description:

The Biomove 3000 is a portable, battery powered EMG triggered neuromuscular electrical stimulator device used as a training system for rehabilitation of paralyzed muscles, mainly after stroke.

The controls of the device are simple to operate. It has only two main control knobs: one to set the gain of the EMG amplifier (sensitivity for picking up the residual electrical muscle signal) and one to set the level for the stimulation impulse to the muscles to be re-educated.

The following parts are supplied with the system: 3-lead Patient Cable, re-usable electrodes (Biotrodes) and a belt for fastening the device to the body of the user. A 5-lead Patient Cable is optional.

H. Intended Use / Indication for Use:

The Biomove 3000 is indicated for:

1. Stroke Rehabilitation by Muscle Re-education
2. Prevention or 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 3000 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. Substantial Equivalence:

There are no unique applications, indications, materials or specifications presented below. Evidence of equivalence has been demonstrated through:

- The Biomove 3000 intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the Biomove 3000 are similar to those of the predicate devices.
- Safety and performance testing.
- Comparative Testing

Therefore, the Biomove 3000 System is substantially equivalent to its predicate devices 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

JAN 27 2005

Ms. Ahava Stein
Regulatory Affairs, Consultant for
Curatronic Ltd.
Beit Hapa'amon (Box 124)
20 Hata'as St., 44425
Kfar Saba
Israel

Re: K042650
Trade/Device Name: Biomove 3000 System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: November 28, 2004
Received: December 6, 2004

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): K042650

Device Name: Biomove 3000 System

Indications for Use:

The Biomove 3000 is indicated for:

1. Stroke Rehabilitation by Muscle Re-education
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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)

for Mark N. Melkerson

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

510(k) Number K042650