510(k) Summary

Premarket Notification [510(k)] summary prepared on November 14, 1997

K974385

FEB 19 1998

Establishment Information

Manufacturer/Summiteer:	Motion Lab Systems, Inc. 4326 Pine Park Drive, Baton Rouge, LA 70809
Contact Name/Phone #	Edmund Cramp Motion Lab Systems, Inc. Phone: (504) 928-4248 Fax: (504) 928-0261

General Device Information

Common/Usual Name	EMG Electrode
Trade/Proprietary Name	MLS Electromyographic preamplifier
Classification Name	Electromyography, Diagnostic - 21 CFR 890.1375
Device Classification	Class II
Performance Standards	None established under section 514

Substantial Equivalence:

The MLS Electromyographic preamplifier is substantially equivalent to the B&L Electrode which is currently legally manufactured under 510(k) K952655

Device Description:

The purpose of the MLS Electromyographic preamplifier is to amplify the myoelectric signals that are generated by muscles when they contract.

Intended Use:

The MLS Electromyographic preamplifier enables researchers and clinicians to acquire EMG signals from active subjects. It is intended to be used in hospital, university and other research facilities to acquire EMG signals for display and analysis by, or under the direction of, a health care professional.

Testing:

A sample of both the predicate B&L Active Electrode and the proposed MLS Electromyographic preamplifier were tested to determine substantial equivalence and relative performance. Myographic recordings from the skin surface over a single muscle were found to be substantially identical in frequency content and power spectrum for both devices.

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Comparison to legally marketed predicate device:

Characteristic	B&L Active Electrode	Proposed MLS device
Intended Use	Ambulatory myoelectric EMG monitoring.	Ambulatory myoelectric EMG monitoring.
Power Source	Isolated external source.	Isolated external source.
Materials / Construction	Styrene case with stainless steel sensor pads.	Polyethylene case with stainless steel sensor pads.
CMRR	95 dB	90 dB
Input Impedance	Greater than 100 MΩ	Greater than 100 MΩ
Power requirements	not stated	500 uA
Signal Bandwidth	20 Hz to 2,000 Hz	DC to 2,000 Hz
Gain	330	20

Conclusion:

Testing done on the MLS Electromyographic preamplifier and the predicate B&L Electrode indicates the proposed MLS Electromyographic preamplifier is as safe and effective and performs a substantially equivalent function to the predicate B&L Electrode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1998

Mr. Edmund Cramp
President
Motion Lab Systems, Inc.
4326 Pine Park Drive
Baton Rouge, Louisiana 70809

Re: K974385
Trade Name: MLS Electromyographic Preamplifier
Regulatory Class: II
Product Code: IKN
Dated: November 18, 1997
Received: November 21, 1997

Dear Mr. Cramp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K974385

Device Name: MLS Electromyographic preamplifier

Indications for Use:

The MLS Electromyographic preamplifier enables researchers and clinicians to acquire EMG signals from active subjects. It is intended to be used in hospital, university and other research facilities to acquire EMG signals for display and analysis by, or under the direction of, a health care professional.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974385

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)