K030714

MAY 16 2003

Peak Motus Motion Measurement System
510(k) Summary

Submitter

Company:	Peak Performance Technologies, Inc. 7388 S Revere Pkwy 901, Centennial, Colorado 80112 USA Tel 303 799 8686, Fax 303 799 8690
Contact:	Larry Scheirman
Prepared:	28 February 2003

Device Name

Trade:	Peak Motus Motion Measurement System
Common:	Motion measurement system
Classification:	System, Optical Position/Movement Recording
Product code:	LXJ

Predicate Devices

Trade Name:	CODA mpx30 Motion Analysis System
510(k) Number:	K982425
Manufacturer:	Charnwood Dynamics Ltd

Introduction

The Peak Motus Motion Measuring System is a mature product. It has been marketed for years for biomechanical research and performance evaluation. The manufacturer has become aware that the system has demonstrated-value and increasing use in medical settings. Therefore, this 510(k) notification is being submitted to properly notify authorities and recognize the system as a legally marketed medical device.

Device Description

The system uses off-the-shelf video cameras, sensors, and computers to collect, quantify, and document human movement in two-dimensional or three-dimensional space. The proprietary elements of the system are Peak's software applications, which run on Microsoft Windows, and an interface box, which can mix and synchronize multiple digital and analog inputs when active data capture is used. The system can effect the capture of real-time video images of motion along with associated sensor information, then sequence the coordinate and sensor information for recording on the computer. Alternatively, the system can use video recordings to provide the motion information. Motion and sensor data are recorded, analyzed, and displayed or reported from the computer.

A typical study involves recording the locations of small reflective markers on subjects as movement occurs. This provides instant coordinate data. Coordinate data may also be gathered from digitized video sequences. Analog sensors, such as force platforms or EMG systems, may also be part of the instrumentation during movement. Their information can be

synchronized, processed, and displayed along with the coordinate information. The system can calculate standard 2-D or 3-D kinematic and kinetic parameters using specific calculation modules. A report generation package displays and reports the data: in raw or processed form, step-by-step, or sequentially.

The Peak Motus system may include software modules, such as

* Advanced video or 3D-optical-motion-capture module
* 2D and/or 3D kinematic calculation and display software
* Analog acquisition module
* 3D pan and tilt module
* KineCalc mathematical analysis module
* Peak Motus Gait Analysis Template

Its hardware comprises a Microsoft Windows computer workstation with proprietary synchronizing and processing boards, and a variety of equipment setups, including

* Purchased cameras, VCRs, lights, calibration frames, high-speed video
* Video, optical-capture, and analog-acquisition boards
* Event synchronization unit
* Analog EMG and force-platform systems and analog-to-digital interface unit (accepts up to 64 sensors)

Movement tracking can be done with or without markers in virtually any collection environment—indoors, outdoors, or even under water. For most medical applications, the tracking is done indoors in a controlled laboratory environment with markers.

The Peak Motus System has standard data reduction algorithms for editing, filtering and calculating linear and angular displacements, velocities, and accelerations. Specialized templates are available for custom calculations: for example, the Peak Motus 3D Gait Analysis Template provides industry-standard gait-analysis calculations such as body segment angles, joint forces, moments, and powers.

The systems' report and display package can print standard reports or can display data on the computer screen through a multimedia-display tool. Parametric data created with the system may be displayed as line graphs, x-y plots, bar graphs, stick figures (with vector overlays), text, and data tables.

Indications for Use

Computer and video system used to quantify and graphically display human movement patterns and techniques for uses such as assessment and training of limb or body motion in gait analysis, prosthetic design, pre/post rehabilitation evaluation, physical therapy, and the like.

Summary of Technological Characteristics

The Peak Motus Motion Measurement System is substantially equivalent to the CODA mpx30 system from Charnwood Dynamics. Both systems acquire motion patterns by optical capture directly linked into a PC computer in real time; using multiple cameras to gather three-dimensional information. In addition, the Peak Motus can acquire these patterns from recorded video. Both systems provide standard biomechanical kinematic and kinetic analyses; displaying the data in tables and graphs on-screen and in printed reports.

Summary of Non-Clinical Performance

Safety

Safety is not an issue with the system. The system uses commonly available consumer and technical equipment with demonstrated safety. The equipment are passive sensing and recording devices; most of which never contact the subject.

Effectiveness

Extensive in-house testing has demonstrated the effectiveness of this system.

Summary of Clinical Performance

In-house and clinical testing by independent third parties has been reported that demonstrates the system's effectiveness and fitness for use in this application.

Equivalence to Predicate Devices

The Peak Motus Motion Measurement System is substantially equivalent to the CODA mpx30 system as a means of measuring the general three-dimensional movements of subjects, including such activities as walking. Both systems provide a non-intrusive optical method of measuring the movement. Both systems acquire the movement data into a host PC, which then analyzes and displays motion data onscreen or in printed reports. Specific, standard gait analysis and other analysis programs are available for these calculations and reports.

The CODA system uses proprietary cameras and LED markers with automatic identification while the Peak Motus system can be used with or without markers with standard video equipment. In addition, the Peak Motus system can use recorded video images to obtain motion information and can incorporate concurrent analog sensor data with its measurements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Larry Scheirman
President
Peak Performance Technologies, Inc.
7388 S. Revere Parkway 901
Centennial, CO 80112

MAY 16 2003

Re: K030714
Trade/Device Name: Peak Motus Motion Measurement System
Regulatory Class: Unclassified
Product Code: LXJ
Dated: February 28, 2003
Received: March 6, 2003

Dear Mr. Scheirman:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

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

510(k) Supplement:

510(k) Number (if known): K030714

Device Name: **Peak Motus Motion Measurement System**

Indications for Use:

Computer and video system used to quantify and graphically display human movement patterns and techniques for uses such as assessment and training of limb or body motion in gait analysis, prosthetic design, pre/post rehabilitation evaluation, physical therapy, and the like.

(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 K030714

(Optional Format 3-10-98)