MyoVision 3G WireFree™ System – 510(k) Summary

Submitter: Precision Biometrics Inc.
PBI/MyoVision
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AUG 1 2013

Date Summary Prepared: July 29, 2013

Trade Name: MyoVision 3G WireFree System
Common Name: Diagnostic Electromyography, Range of Motion, and Thermography
Classification Name: Diagnostic electromyography (21 CFR 890.1375)
Classification Panel: 89, Physical Medicine
Product Code: IKN (Secondary procodes HCC, KQX, HCS)
Regulatory Class: II
Predicate: Fasstech, Insight Millennium III (K023209)

Device Description: The MyoVision 3G WireFree™ System consists of handheld scanner devices which receive and transmit signals to a system hub. The data from the devices is displayed on a personal computer.

The MyoVision 3G WireFree™ System is designed to measure and visually present physiological signals corresponding to muscle activity (surface EMG), range of motion, and maps of heat generated by the human body. This device is intended to provide the clinician with a patient's EMG activity, skin temperature, and range of motion during therapies that include muscle relaxation training and re-education.

The MyoVision 3G WireFree™ System consists of four (4) physiological parameter scanners, a system hub, and proprietary application software. The four scanners are the

- static surface EMG scanners (ScanVision™),
- dynamic surface EMG scanner (DynaVision™),
- range of motion inclinometers (FlexVision™), and
- thermograph (ThermoVision™).

Data collected by the scanners is wirelessly transmitted to a computer via a system hub (either SoloVision™ or PhysioMonitor™) for data processing, data storage, and visual display. The wireless feature provides for data collection efficiency and ease of use. The proprietary application software was developed and validated by Precision Biometrics, Inc. (PBI).

Intended and Indications for Use:	The PBI MyoVision 3G WireFree™ Systems are indicated to provide the clinician with EMG activity, skin temperature, angles of the patient's motion information during therapies that include muscle relaxation training and re-education.
Technological Character Differences:	There are some differences between the predicate device and the MyoVision 3G WireFree System™ due to the elimination of the wired connection to the system hub as well as some product refinements based on AAMI Guidelines. The most significant difference between the predicate and PBI's system is the communication technology between the handheld scanners and the system hub. The Fasstech devices require the use of proprietary cables whereas the MyoVision 3G WireFree™ System does not require cables. The MyoVision 3G WireFree™ System's communication technology uses 3G wireless low-power transmission similar to Bluetooth (Class III) technology, which has been tested to ensure safety and effectiveness in a clinical setting. The other differences have to do with refinements to the measurement methodology based on AAMI Guidelines for these types of devices. For instance, the plethsmograph, algometer, and single inclinometer of the Fasstech are not included in the MyoVision 3G WireFree™ System because PBI's research into these device types shows their use is optional, not needed, or ineffective.

Non-Clinical Performance Data:

Performance testing per standardized methods and PBI test protocols for bench data was conducted and provides support that the MyoVision 3G WireFree™ System is substantially equivalent to currently marketed predicate devices. Non-clinical performance test protocols and results demonstrate that, in consideration of its intended use, the design, labeling, and packaging of the MyoVision 3G WireFree™ System is compliant with all applicable standards, including the following:

- ANSI/AAMI EC12:2006, Disposable ECG electrodes, 2000
- IEC 60601-1:1988 Medical Electrical Equipment – Part 1: General Requirements For Safety and Essential Performance.
- IEC 62304:2006 Medical device software -- Software Lifecycle processes: 2006
- ISO 14971:2007-2nd Edition; Medical devices -- Application of risk management to medical devices
- ISO 15223:2000 Medical Devices - Symbols to be Used with Medical Devices Labels, Labeling and Information to be Supplied
- IEC 60601-2-40:1998 Medical Electrical equipment - Part 2-40: Particular Requirements for Safety of Electromyographs and Evoked Response Equipment
- ISO 13485:2003; Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- IEC 60601-1-2; Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004))
- Draft Guidance for Industry and FDA Staff: Radio-Frequency Wireless Technology in Medical Devices

Clinical Performance Data:

Clinical data was not necessary to support that the MyoVision 3G WireFree™ System is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 1, 2013

Precision Biometrics, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K123399
Trade/Device Name: Myovision 3G WireFree System
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: Class II
Product Code: IKN, HCC, KQX, HCS
Dated: July 16, 2013
Received: July 17, 2013

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123399

Device Name: MyoVision 3G WireFree™ System

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The PBI MyoVision 3G WireFree™ System is indicated to provide the clinician with EMG activity, skin temperature, angles of the patient's motion information during therapies that include muscle relaxation training and re-education.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123399