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ABN: 15 129 742 409

510(K) SUMMARY

[as required by section 807.92(c)]

JUL 1 1 2014

ViMove

510(k) Number K131094

Applicant Name:

dorsaVi Ltd
Level 1, 120 Jolimont Road
East Melbourne 3002,
Victoria, Australia

Company Contact:

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Date 510K Summary Prepared:

09 July 2014

Contact Person:

Name: Shoshana (Shosh) Friedman, RAC
Address: 1914 J N Pease Pl., Charlotte, NC 28262
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Fax: (704) 899-0098
E-mail: shosh@pushmed.com

Trade Name:

ViMove

Classification:

The ViMove is classified as a Diagnostic Electromyograph (product code IKN) according to 21 CFR 890.1375, with subsequent product codes HCC (Biofeedback Device) and KQX (Goniometer).

Predicate Devices:

1. Insight Discovery manufactured by Fasstech (K063447).
2. Vicon manufactured by Oxford Medilog, Inc. (K811172).

dorsaVi
Inspiring the world to move

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Device Description:

ViMove is comprised of five key components:

- 4 Wireless Sensors (2 for movement and 2 for muscle activity)
- Disposable Application Pads for holding the wireless sensors: movement (DAP-M) and muscle (DAP-E) sensors
- Recording and Feedback Device (RFD) is worn in the patient's pocket or within one meter of the sensors
- Recharging Cradle
- ViMove software package

Intended Use/Indications for Use:

ViMove is a wireless medical device that measures, records, and reports movements and muscle activity of the lower back / lumbar spine. The system also measures range of motion in the sagittal and coronal anatomical planes.

Technological Characteristics:

ViMove is substantially equivalent to the Insight Discovery as both devices are non-invasive, multi-modality physiological monitoring devices. Both devices incorporate surface EMGs to measure muscle activity, and inclinometers to measure range of motion.

Both devices use dedicated software to acquire data to provide real time biofeedback and generate a report for the healthcare practitioner, and use Acrylonitrile Butadiene Styrene (ABS) for the physical material. The technological similarities between ViMove and the predicates Insight Discovery and Vicon are summarized in the Table below.

	ViMove	Insight Discovery	Vicon
510(k) Number	K131094	K063447	K811172
Manufacturer	dorsaVi	Fasstech	Oxford Metrics Inc.
Product Code	IKN HCC KQX	IKN HCC	IKN
Non-invasive medical device	Yes	Yes	Yes

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Surface Electromyography	Yes	Yes	No
Provides Real time biofeedback to the user	Yes	Yes	Yes
Energy is not delivered to the muscles, energy is detected from muscle activity only	Yes	Yes	Yes
Wireless Inclinometer	Yes	Yes	Yes
Rechargeable batteries in the wireless sensors	Yes	Yes	N/A
ISM band - 2.4GHz	Yes	Yes	N/A
Real-time objective measurement of Range of Motion	Yes	Yes	Yes
Dedicated Software	Yes	Yes	Yes
Report generated for health Care Professional	Yes	Yes	Yes
ABS used for Case	Yes	Yes	No
Device used on Spine	Yes	Yes	Yes
Isolated USB/Ethernet to connect to PC	Yes	Yes	Yes

Performance Data:

ViMove's performance characteristics were assessed against the Insight Discovery by comparing intended use, technological characteristics, and performance characteristics. Performance data assessed included measurement capabilities, accuracy, and compliance to international electrical safety and electromagnetic compatibility standards.

The accuracy of the ViMove was tested and compared to the accuracy of the Vicon and found to be substantially equivalent for measuring range of motion in the sagittal and coronal anatomical planes.

ViMove has been tested and complies with the following voluntary standards:

ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice
IEC 60601-1	Medical electrical equipment, Part 1: General requirements

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	for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO 15223	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements
ISO 10993-5	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
16 CFR 1500	Guidelines of the Federal Hazardous Substances Act (FHSA) Regulations for Cytotoxicity, Sensitization and Primary Skin Irritation tests.
IEC 62304	Medical device software - Software life cycle processes

Additionally, bench testing has been performed to ensure that the components of the ViMove can withstand crush and shock (drop) tests with no noticeable change or degradation of surfaces, color or structure in accordance to IEC 60601-1.

The DAPs when assembled with the MD sensors of the ViMove have been tested to ensure that they are able to withstand a drop test performed from 1.5 meters on to hardwood floor with a concrete base and a crush force of 25kg

The RFD is required to withstand a drop from 2m on to a hardwood floor with a concrete base without functional damage and a crush force of 25kg.

Clinical Data:

Not applicable.

Conclusion:

Based on the information provided in this submission, ViMove is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2014

dorsaVi Ltd.
c/o Ms. Shoshana Friedman
Push-Med, LLC.
1914 J N Pease Pl.
Charlotte, NC 28262

Re: K131094
Trade/Device Name: ViMove
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: Class II
Product Code: IKN, HCC, KQX
Dated: June 12, 2014
Received: June 13, 2014

Dear Ms. Friedman:

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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,

Carlos L. Peña -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131094

Device Name
ViMove

Indications for Use *(Describe)*
ViMove is a wireless medical device that measures, records, and reports movements and muscle activity of the lower back / lumbar spine. The system also measures range of motion in the sagittal and coronal anatomical planes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
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