DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 14, 2017

Dorsavi Ltd
% Bosmat Friedman
Regulatory Consultant
Pushmed LLC
1208-12 Rockford Rd
Toronto, L4J 7Y9 CA

Re: K163150
Trade/Device Name: ViMove2
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyograph
Regulatory Class: Class II
Product Code: IKN, HCC, KQX
Dated: June 16, 2017
Received: June 16, 2017

Dear Bosmat 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" (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 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,

Michael J. Hoffmann -S

for 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)*
K163150

Device Name
ViMove2

Indications for Use *(Describe)*
ViMove2 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (as required by section 807.92(c))

VIMOVE2

510(K) NUMBER

K163150

I. SUBMITTER

dorsaVi Ltd
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Date Prepared: Oct 15, 2016

II. DEVICE

Name of Device:	ViMove2
Trade Name:	ViMove2
Common or Usual Name:	Electromyograph and Goniometer with BioFeedback System
Classification:	Diagnostic Electromyograph Product Code: IKN Regulation No: 890.1375 Regulatory Class: II Classification Panel: Physical Medicine Biofeedback Device Product Code: HCC Regulation No: 882.5050 Regulatory Class: II Classification Panel: Neurology Goniometer Product Code: KQX Regulation No: 888.1500 Regulatory Class: I Classification Panel: Orthopedic

III. PREDICATE DEVICE

Predicate Device(s): ViMove manufactured by dorsaVi Ltd (K142494) (This predicate has not been subject to any product recalls).

IV. DEVICE DESCRIPTION

ViMove2 is a wireless electronic device used by healthcare professionals to accurately measure, record and analyze movement and muscle activity of the lower back. The device objectively measures, records and analyzes angular movement and muscle activity.

Under the direction of the healthcare professional, the software guides the patient through a series of dynamic movements and static postures in standing and sitting positions. ViMove2 then measures the range of motion and muscle activity, streams the data live via BTLE to a host device, e.g. PC, tablet or smart phone, and generates a personalized assessment report including comparisons to normative values.

ViMove2 is comprised of the following key components:

- 4 Wireless Sensors (2 movement and 2 muscle activity)
- Disposable Application Pads for attaching sensors to the patient.
- ViMove software package

V. INDICATIONS FOR USE

ViMove2 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified ViMove presented in this 510(k) is substantially equivalent to the predicate in terms of intended use, fundamental scientific technology, operating principles and mechanism of action. The main differences between the devices are a reduction in size of the movement (MDM) and muscle activity (MDE) sensors; changes to battery, electronic components, circuitry and DAPs to accommodate the smaller sensors, the addition of Bluetooth compatibility (BTLE), changes to the user interface and format of the assessment report. The RFD Biofeedback device utilized in the predicate device are no longer required for the modified ViMove2 device.

A summary of the differences between the ViMove predicate and ViMove2 is provided in Table 1 below. A more detailed comparison is provided in Attachment G.

Table 1. Summary Comparison of the Modified ViMove and Predicate

	Predicate ViMove	**ViMove2**
510(k) Number	K142494	K163150
Manufacturer	dorsaVi Ltd	dorsaVi Ltd
Product codes	IKN HCC KQX	IKN HCC KQX
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.	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.
Non-invasive medical device	Yes	Yes
System Components	• 4 Wireless Sensors (2 movement MDMs and 2 muscle activity MDEs) • Disposable Application Pads (DAPs) for holding the wireless sensors (DAP-M for movement and DAP-E for muscle sensors) • Recording and Feedback Device (RFD) • Recharging Cradle with AC Adaptor • USB • ViMove software	• 4 Wireless Sensors (2 movement MDMs and 2 muscle activity MDEs) • Disposable Application Pads (DAPs) for holding the wireless sensors (DAP-M for movement and DAP-E for muscle sensors) • AC Adaptor • USB • ViMove software • Recharging Cradle with AC Adaptor
Performance data submitted to support range of motion measurements	Flexion Extension Lateral Flexion Pelvic Tilt Single Leg Standing Sitting (normal, upright and slouched)	Flexion Extension Lateral Flexion Pelvic Tilt Single Leg Standing Sitting (normal, upright and slouched)
Assessment report includes normative values for ROM	Yes	Yes
Provides real time biofeedback to the user	Yes (via RFD device)	Yes (directly to host device)
Movement Sensor Type	Accelerometer Gyroscope Magnetometer	Accelerometer Gyroscope Magnetometer

Wireless Type	ANT	BTLE
Muscle Activity sensor	Surface EMG	Surface EMG
Battery Type	Lithium-Polymer	Lithium-Polymer
Includes DAPs for holding the wireless sensors	Yes	Yes
Charging	Recharging Cradle or AC Adaptor (5VDC)	AC Adaptor, USB Port (5VDC) or Recharging Cradle
Includes dedicated software	Yes	Yes
Rechargeable batteries in the sensors	Yes	Yes
Real-time objective measurement of range of motion	Yes	Yes
Report generated for Healthcare Professional	Yes	Yes
Includes Bluetooth compatibility (BTLE)	No	Yes

VII. PERFORMANCE DATA

In support of the modifications presented in this 510(k), testing was performed to validate ViMove2 for assessment of lumbo-pelvic range of motion (ROM) and posture, including flexion, extension, lateral flexion, normal standing lordotic angle, pelvic tilt (sitting and standing) and various sitting postures (normal, upright and slouched).

Additional design verification was performed on the ViMove2 in accordance with 21 CFR 820.30, including testing to demonstrate compliance testing to the following standards:

ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
IEC 60601-1	Medical electrical equipment, Part 1: General requirements 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
IEC 62366	Medical devices - Application of usability engineering to medical devices.
IEC 62304	Medical device software - Software life cycle processes.

VIII. CONCLUSIONS

Based on the information provided in this submission, the modified ViMove2 is substantially equivalent to the predicate ViMove device and does not raise any questions relating to safety and/or effectiveness.

The modifications proposed in the ViMove2 do not affect the intended use, fundamental scientific technology, principles of operation or clinical application when compared to the predicate device.