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

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
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)
- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

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

**ViMove2**

**510(k) NUMBER**

**K163150**

**I. SUBMITTER**

dorsaVi Ltd  
Level 1, 120 Jolimont Road  
East Melbourne 3002, Australia  
Establishment Registration No. 3010872373  
Owner Operator Number: 10046462

Contact Person: Dan Ronchi  
Phone: +61-(0)3-9652-2191  
Fax: +61-(0)3-8610-1024  
Email: dr@dorsavi.com

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 ViMove

<table>
<thead>
<tr>
<th></th>
<th>Predicate ViMove</th>
<th>ViMove2</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) Number</td>
<td>K142494</td>
<td>K163150</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>dorsaVi Ltd</td>
<td>dorsaVi Ltd</td>
</tr>
<tr>
<td>Product codes</td>
<td>IKN, HCC, KQX</td>
<td>IKN, HCC, KQX</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Non-invasive medical device</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>System Components</td>
<td>4 Wireless Sensors (2 movement MDMs and 2 muscle activity MDEs)</td>
<td>4 Wireless Sensors (2 movement MDMs and 2 muscle activity MDEs)</td>
</tr>
<tr>
<td></td>
<td>Disposable Application Pads (DAPs) for holding the wireless sensors (DAP-M for movement and DAP-E for muscle sensors)</td>
<td>Disposable Application Pads (DAPs) for holding the wireless sensors (DAP-M for movement and DAP-E for muscle sensors)</td>
</tr>
<tr>
<td></td>
<td>Recording and Feedback Device (RFD)</td>
<td>AC Adaptor</td>
</tr>
<tr>
<td></td>
<td>Recharging Cradle with AC Adaptor</td>
<td>USB</td>
</tr>
<tr>
<td></td>
<td>ViMove software</td>
<td>ViMove software</td>
</tr>
<tr>
<td>Performance data submitted to support range of motion measurements</td>
<td>Flexion Extension Lateral Flexion Pelvic Tilt Single Leg Standing Sitting (normal, upright and slouched)</td>
<td>Flexion Extension Lateral Flexion Pelvic Tilt Single Leg Standing Sitting (normal, upright and slouched)</td>
</tr>
<tr>
<td>Assessment report includes normative values for ROM</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Provides real time biofeedback to the user</td>
<td>Yes (via RFD device)</td>
<td>Yes (directly to host device)</td>
</tr>
<tr>
<td>Movement Sensor Type</td>
<td>Accelerometer Gyroscope Magnetometer</td>
<td>Accelerometer Gyroscope Magnetometer</td>
</tr>
</tbody>
</table>
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 10993-10: 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.