



ASX ANNOUNCEMENT

1 June 2015

### **FDA approves ViMove for expanded use in the United States**

**Melbourne, Australia** – Medical device company dorsaVi Ltd (ASX: DVL) has received 510(k) clearance by the US Food and Drug Administration expanding the use of ViMove in the United States.

The expanded functionality and labelling is highly significant because for the first time in the USA it permits the use of ViMove to display lower back and pelvic range of motion from healthy patients (normative data). Clinicians and their patients will now be able to compare how their movements are tracking against a “normal” population based on their age group, and help guide therapy decisions and rehabilitation accordingly.

Importantly, this new expanded labelling also permits dorsaVi to record, assess and report on additional static postures including lumbar lordosis (natural standing posture) and on various sitting postures. The inclusion of the pelvic movement data allows clinicians to independently isolate lumbar spine and pelvic movements.

As part of the submission to achieve the new labelling, the ViMove data was validated against sophisticated optical tracking sensors (Vicon) used in biomechanical laboratories, and with a marker set clinically validated against Magnetic Resonance Imaging (MRI) for a range of lumbopelvic movements. All ViMove data for standing and sitting postures was accurate to within 5 degrees.

“This is an important breakthrough for clinicians and patients,” said Andrew Ronchi, CEO of dorsaVi.

ViMove was previously 510(k) cleared in July 2014 and with this latest clearance, improves the clinical capabilities of ViMove.

John Kowalczyk, President of dorsaVi USA added: “510(k) clearance by the FDA, which enables the expanded use of ViMove in the United States, is a major milestone for dorsaVi and will allow us to increase our marketing efforts to physical therapists and health care professionals globally.”

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**For more information or to arrange an interview, please contact:**

Kellie Hanrick (Media)  
Buchan Consulting  
[khanrick@buchanwe.com.au](mailto:khanrick@buchanwe.com.au)  
0413 681 346

Rebecca Wilson (Investor Relations)  
CEO, Buchan Consulting  
[rwilson@buchanwe.com.au](mailto:rwilson@buchanwe.com.au)  
(03) 9866 4722 / 0417 382 391

**About dorsaVi**

dorsaVi Ltd (ASX: DVL) is an ASX company focused on developing innovative motion analysis device technologies for use in clinical practice, elite sports, and occupational health and safety. dorsaVi believes its wearable sensor technology enables – for the first time – many aspects of detailed human movement and position to be accurately captured, quantified and analysed outside a biomechanics lab, in both real-time and real situations for up to 24 hours.

Our technology has application across three sectors:

- **Clinical:** ViMove is transforming the management of patients, by providing objective assessment, monitoring outside the clinic and tailored biofeedback. ViMove is currently used by medical and allied health practice in Australia, New Zealand and the United Kingdom.
- **Elite Sports:** Elite sports medical teams are using ViPerform to screen and assess risk of injury, take preventative action, optimize technique, improve athlete rehabilitation, and make better return to competition decisions. ViPerform is being used by AFL and NRL clubs in Australia, clubs in the Barclays Premier League, Australian and Victorian Institutes of Sport, Cricket Australia and various Olympic teams and athletes internationally.
- **OHS:** We combine innovation, measurement and quality to reduce workplace incidents, costs, meet compliance and improve brand reputation. ViSafe enables employers to assess risk of injury for employees as well as test the effectiveness of proposed changes to workplace design, equipment or methods based on objective evidence. ViSafe has been used by major corporations including Coles, Woolworths, Toll, Toyota, Orora (formerly Amcor), Crown and BHP Billiton. Australian Workplace Compliance (AWC) delivers risk mitigation through compliance to OHS, Quality Management Systems, Company Policy and Process.

Further information is available at [www.dorsavi.com](http://www.dorsavi.com).

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