



Reflexonic LLC Cleared for OTC Sales of Viberect ED Treatment in the US

Urological medical device company wins FDA clearance for OTC sales of novel product with assistance from Emergo.

FREDERICK, MD, USA, October 20, 2014 /EINPresswire.com/ -- Reflexonic LLC, developer of the Viberect non-pharmaceutical device for treating erectile dysfunction (ED) in men, has achieved Food and Drug Administration clearance to market the product over the counter in the US.

Viberect is intended for men with mild to moderate ED symptoms due to disease, age, medical side effects, depression, or other issues. The device functions via high-frequency and amplitude vibratory stimulation in order to activate sexual pathways. Multiple clinical studies have supported this modality for its intended purposes. Reflexonic Viberect is a safe, noninvasive, and effective first line treatment option for men with erectile dysfunction. It is the first and only medical vibratory device in the world for ED treatment.

Viberect is already registered for sale so far in the US, European Union, Australia, Canada and India. Now, with support from Austin, Tex.-based medical device regulatory consulting firm Emergo, Reflexonic may sell Viberect directly to US users without a prescription.

"Viberect is now available to the general US population over the counter," says Dr. Kambiz Tajkarimi, Founder and President of Reflexonic. "Previously, prescription requirements for Viberect had impeded our sales because many men do not wish to discuss ED symptoms with their healthcare providers."

Dr. Tajkarimi explains that Reflexonic began working with Emergo in 2011 to obtain FDA 510(k) clearance for Viberect in the US. Since then, Emergo has assisted the manufacturer in obtaining ISO 13485 quality system certification, CE Marking in Europe, Health Canada licensing and registration with the Australian Therapeutic Goods Administration.

"In 2011, we received FDA clearance for prescription use in the US. In the past 2 years, with Emergo's help we have successfully secured entire production cycle and partnered with highest quality manufacturers, right here in America. We are proud to be made in USA." Dr. Tajkarimi explains.

"We have worked with Reflexonic to bring their non-invasive, non-pharmaceutical ED treatment to market in North America, Europe and Asia, and have now helped to expand the user base for

Viberect in the US,” says Julie Powell, Vice President of Quality Assurance Consulting at Emergo. “Now, by being able to sell Viberect over the counter, Reflexonic can tap even further into the US market.”

About Reflexonic, LLC

Reflexonic is an urologist-owned and operated US medical device company dedicated to creating simple, intelligent, and physiological hand-held devices that millions of men can use to restore and preserve their sexual and urinary health. Further information can be found at www.reflexonic.com

About Emergo

Emergo is a global medical device consulting firm providing a wide range of services for [device registration](#), QMS compliance, clinical trial management, in-country representation, reimbursement and distributor search consulting. Further details at www.emergogroup.com

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