

FDA Okays First Device for Restless Legs Syndrome

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The US Food and Drug Administration (FDA) today granted commercial clearance of the first device to help improve quality of sleep in patients with primary restless legs syndrome (RLS), the company announced.

The device (*Relaxis*, Sensory Medical Inc) is a low-profile pad; the patient lies in bed and places his or her legs on the pad, which provides vibratory counterstimulation that gradually ramps down and shuts off. The approval is based on a [meta-analysis](#) and a [pooled analysis](#) of 2 randomized, multicenter clinical trials that showed the device was superior to a placebo pad for improving sleep quality in patients with RLS, the company noted in a statement.

The device is a noninvasive, nonpharmacologic alternative for patients who now are treated variously by getting up to move their legs to relieve symptoms (which interrupts sleep) or using dopaminergic agents, anticonvulsants, opioids, muscle relaxants, or sleep medications (including benzodiazepines), the statement pointed out.



Relaxis device. *Courtesy of Sensory Medical Inc*

"Unfortunately, some of these medications present the risk of dependence or addiction, and are considered inappropriate for certain RLS sufferers, including pregnant women and dialysis sufferers," the release adds. "NINDS [National Institute of Neurological Disorders and Stroke] reports that some drugs also have been found to actually worsen patients' RLS symptoms over time, despite initially providing relief."

The company's Web site notes that use of the pad may also worsen RLS symptoms, but worsening resolved within 3 weeks of stopping use of the device, returning to pretreatment symptom levels. Other adverse effects include leg cramping, soreness, pain, and motion sickness.

Sensory Medical Inc plans to exhibit the new system, which will be available on a prescription-only basis in the United States starting in the third quarter of 2014, in booth 1018 at SLEEP 2014, the American Academy of Sleep Medicine's annual meeting of the Associated Professional Sleep Societies, beginning June 2 at the Minneapolis Convention Center, the company notes.