Looking Ahead In the Wake of CES Device Reclassification

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Alpha-Stim AID

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In June, the Food and Drug Administration (FDA) announced its intention to reclassify cranial electrotherapy stimulation (CES) devices from a class III to a class II designation, ending a battle that the CES industry has fought with the governmental agency for more than 22 years. The move is expected to dramatically change the playing field for the industry as companies in this space shift from a defensive position into more intense marketing.

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One of the companies that took a leading role in this battle and is most affected by this change, is Electromedical Products International, Inc. (EPI). EPI, which in addition to offering its CES devices to healthcare professionals around the world, has been the only provider of such devices to the U.S. Army and the Veterans Affairs Medical Centers since 2005 as a treatment for depressive disorders, anxiety and insomnia.

Tracey Kirsch, President of EPI, believes that this change in classification will have ramifications for the industry and for EPI in

battle," she said. "It has been at the center of how we do business. With this roadblock removed, that energy is being refocused on continued product evolution, a new marketing campaign and expanding business opportunities."

"We have long known that CES is safe and effective, used around the world to treat conditions like depression, anxiety, insomnia and pain, but with the FDA classifying CES devices like our own Alpha-Stim, as class III, we were put into the same category as highly regulated 'high risk' medical devices such as pacemakers and heart valves, which we always have felt was an improper designation," Kirsch said.

Fighting the classification battle with the FDA has taken time and energy from the entire senior management team as sales, marketing and product development were hamstringed by the designation. According to Kirsch, she knows first-hand that when a company is focused on a fight with the FDA, it is hard to build the business, as that resulting "limbo" can impede even growth abroad. She cites as an example that government agencies in other countries often take their lead from the FDA, which limits growth opportunities. In addition, here in the U.S., obtaining insurance approval for Alpha-Stim has proven to be a challenge, as insurers, seeing the class 3 designation, are wary to compensate doctors and patients for treatment. But while the controversy with the FDA raged, EPI continued to take advantage of technological advances to assure the Alpha-Stim devices reflected the most advanced features possible. Some of these included such changes as:

- Newer, more comfortable ear clips
- A repositioned dial on the case to assure that the setting couldn't be accidentally changed
- New timer settings and controls
- Easy-to-read back-light feature in low-light situations

Kirsch says while some of these changes sound small, they're all part of the product design to assure ease of use, maximum functionality and a desire to deliver CES with the latest technology.

With the reclassification of CES devices in sight, the goal now is on expanding EPI's reach into new markets and focusing on education here in the U.S., so more medical professionals – and the patients who can benefit from the therapy – can learn about Alpha-Stim devices and better understand how CES treatment can be a good option to manage mood disorders and treat pain.