MED DEVICE ONLINE

News Feature | January 26, 2016

FDA Downgrades Certain Cranial Electrotherapy Devices To Class II

By Jof Enriquez,
Follow me on Twitter @jofenriq

The U.S. Food and Drug Administration (FDA) plans to downgrade cranial electrotherapy stimulator (CES) devices, intended to treat insomnia and/or anxiety, from Class III to Class II devices, subject to premarket notification. However, the agency has proposed that CES devices aimed at treating depression require a premarket approval application (PMA).

In a proposed administrative order detailing its plans, FDA distinguished cranial electrotherapy stimulation from the similar electroconvulsive therapy (ECT) by defining a CES device as a prescription device which applies electrical current that is not intended to induce a seizure to a patient's head to treat psychiatric conditions. CES is an FDA-approved, non-invasive treatment modality for pain, insomnia, anxiety, and/or depression in clinical and home settings. CES devices have been designated Class III since 1976 because the safety and effectiveness of said devices had not been demonstrated by data existing at that time. Despite manufacturer petitions over the next few decades for a re-classification, a 2012 Neurological Devices panel recommended that CES devices be kept in Class III.

Based on new and valid scientific evidence, however, the agency is now reconsidering its position. It proposes a re-classification of CES devices from Class III to Class II, albeit only for the treatment of insomnia and/or anxiety, and with special controls and general controls (including prescription-use restrictions and 510(k) notification requirements) in place.

"FDA has reconsidered the information before the Agency, including the deliberations of the 2012 Panel meeting and the reclassification petitions submitted for these devices, and has determined that there is sufficient information to establish special controls," the agency explains

in the order. Those special controls, together with general controls, "will provide a reasonable assurance of safety and effectiveness when applied to CES devices intended to treat insomnia and/or anxiety."

FDA in 2014 withdrew a proposal calling for PMAs for CES, after receiving comments overwhelmingly against such action. In the latest order, however, FDA proposes to require CES device manufacturers to submit PMAs for devices aimed at treating depression because there is insufficient information that could support a down-classification from Class III at this time.

"The body of evidence is not sufficiently robust for FDA to determine that there is a reasonable assurance of safety and effectiveness for CES treatment of depression," the agency explains in the order. "Among the intended uses of insomnia, anxiety, and depression, the evidence supporting the effectiveness of CES for treating depression is the weakest."

FDA's intent to re-classify CES devices from Class III into Class II even for a few indications would open up the market for manufacturers.

"I anticipate that the down-classification of CES devices will result in our obtaining an insurance code for CES, which opens new doors for us and benefits health care providers and patients," writes Tracey B. Kirsch, president of Electromedical Products International, which makes the Alpha-Stim device, in an *MDO* guest column. "We plan to explore new indications for Alpha-Stim, and work on obtaining clearance for use in other therapeutic applications."

FDA is accepting comments on the proposed order until April 21, 2016.