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FDA Lowers Age For Electroshock Devices From 18 To 13 In Final Order; Gives Makers Of Down-Classified ECTs 6 Months To Submit 510(k) Amendments

by Shawn M. Schmitt

A Dec. 26 final administrative order from FDA says people as young as 13 who suffer from major depressive disorders can now be treated with electroconvulsive therapy (ECT) devices that have been newly down-classified by the US agency, from high-risk class III to moderate-risk class II with special controls. Manufacturers of ECT devices covered by the final order have 180 days to submit an amendment to their product's 510(k) that shows how their device meets the special controls. Meanwhile, makers of class III ECT devices that were not redesignated as class II must file a pre-market approval application with FDA within 90 days.

People as young as 13 who suffer from major depressive disorders can now be treated with electroconvulsive therapy (ECT) devices that have been newly down-classified by US FDA, the agency says in a *Dec. 26 final administrative order*.

The final order places high-risk, pre-amendment class III ECT devices – those already on the market before FDA enacted its *Medical Device Amendments of 1976* – into a more moderate-risk designation of class II with special controls.

"After examination of the totality of the scientific evidence, FDA continues to believe that there is sufficient evidence to establish special controls that, together with general controls, provide a reasonable assurance of SE [safety and effectiveness] to reclassify ECT to class II," the agency says in its order.

A highly controversial procedure, ECT involves applying up to 460 volts of electricity to the brain to treat severe major depressive episodes associated with major depressive disorder or bipolar disorder in patients who are treatment-resistant or require a rapid response due to the severity of their psychiatric or medical condition.

The devices were reclassified as part of the device center's ongoing "*515 Program Initiative*" to address all remaining pre-amendment class III device categories by designating the need for a PMA, or down-classifying them to class II or the low-risk class I.

FDA says it considered more than 400 scientific articles when determining whether to lower the patient age for the ECT devices.

FDA outlined plans to down-classify the ECT devices in a *December 2015 proposed order*, for which the agency says it received and considered more than 3,400 comments. But the new final order goes further than the proposal by lowering the patient age for the devices from 18 to 13. (Also see "*Electroconvulsive Therapy Devices: FDA Proposes 510(k), Special Controls*" - Medtech Insight, 29 Dec, 2015.)

FDA says it made the age change after reviewing published scientific literature, comments and literature from the public, clinical practice guidelines, and Medical Device Reports.

"The reevaluation of the scientific evidence presented to and discussed at the 2011 panel meeting, and the review of additional post-2011 scientific information that was provided to FDA in comments to the proposed order, further supports this finding," the agency says.

FDA is referring to a January 2011 meeting of its Neurological Devices Panel, during which panel members voted 10-8 that the ECT devices should maintain their class III status and that the agency should require PMAs for the devices. FDA cast aside the panel's recommendations in its 2015 proposal. (Also see "*FDA Panel Endorses PMAs For Electroshock Therapy Devices*" - Medtech Insight, 7 Feb, 2011.)

The agency says it considered more than 400 scientific articles when determining whether to lower the patient age for the devices.

"Some of the articles included studies that investigated the SE of ECT for catatonia, mania, schizophrenia, and schizoaffective disorder, and use of ECT in children, adolescents and adults,"

FDA says in defense of the age change.

"Many of these articles also provided information on research published since 2010, after the literature review was conducted for the 2011 panel on classification of ECT devices," the agency adds. "In addition, 29 articles referenced in the ECT public dockets contain valid scientific evidence on the SE of ECT in the adolescent subpopulation" – that is, patients aged 13 to less than 18 years.

6 Months To Meet Special Controls

Makers of ECT devices covered by the final order have 180 days to submit an amendment to their product's 510(k) that shows how their device meets these special controls:

- The technical parameters of the device, including waveform, output mode, pulse duration, frequency, train delivery, maximum charge and energy, and the type of impedance monitoring system must be fully characterized to ensure that the device performance characteristics are consistent with existing clinical performance data.
- Nonclinical testing data must confirm the electrical characteristics of the output waveform.
- Components of the device that come into human contact must be demonstrated to be biocompatible.
- Performance data must demonstrate electrical and mechanical safety, and the functioning of all safety features built into the device, including the static and dynamic impedance monitoring system.
- Appropriate analysis/testing must validate electromagnetic compatibility.
- Appropriate software verification, validation and hazard analysis must be performed.
- Performance data must demonstrate electrical performance, adhesive integrity, and physical and chemical stability of the stimulation electrodes.

As part of the special controls, manufacturers must also ensure that device labeling includes a whole slew of information, including a summation of clinical testing, data related to "generic" adverse events involving ECT treatment, and relevant contraindications, warnings and precautions – just to name a few.

FDA points out that while the amendment will be added to the device firm's 510(k) file, it "will not serve as the basis for a new substantial equivalence review. A submitted 510(k) amendment

... will be used solely to demonstrate to FDA that an ECT device is in compliance with the special controls."

And for class II ECT devices "that have not been legally marketed prior to Dec. 26, 2018, or models that have been legally marketed but are required to submit a new 510(k) ... because the device is about to be significantly changed or modified, manufacturers must obtain 510(k) clearance, among other relevant requirements, and demonstrate compliance with the special controls ... before marketing the new or changed device," the agency notes.

PMAs Needed For Some ECT Devices Within 90 Days

Meanwhile, makers of class III ECT devices that were not redesignated as class II must file a pre-market approval application with FDA within 90 days.

The agency is requiring PMAs for ECT devices intended to treat schizophrenia, bipolar manic states, schizoaffective disorder, schizophreniform disorder and catatonia in patients aged 13 and younger, or patients older than 13 who are not treatment-resistant, or who do not require a rapid response due to the severity of their psychiatric or medical condition.

Manufacturers "will be permitted to continue marketing such class III devices during FDA's review of the PMA, provided that the PMA is timely filed," the agency says.

From the editors of The Gray Sheet