Neurological Devices Advisory Panel
Electroconvulsive Therapy (ECT) Devices
515(i) Reclassification

FDA
Center for Devices and Radiological Health
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Device Classification and Reclassification

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The Act divided the arena of medical devices into either:

- Preamendments Devices or
- Postamendments Devices

Depending on when the devices were introduced into interstate commerce for commercial distribution
Classification of Preamendments Devices

Preamendments devices are classified after FDA has:

- Received a recommendation from a device Classification Panel
- Published the Panel’s recommendation for comment, along with a PR classifying the device; and
- Published a FR classifying the device
Reclassification of Preamendments Devices

FDA may reclassify a preamendments device:

• In a proceeding that parallels the initial classification proceeding
• Based upon new information respecting a device either on FDA’s own initiative or upon the petition of an interested person
Postamendments devices are automatically classified into Class III
Those devices remain in Class III and require premarket approval, unless and until
- the device is reclassified into Class I or II
- FDA issues a SE determination
- the device is classified into Class I or II via the Evaluation of Automatic Class III Designation \((de\ novo\ review)\)
Reclassification of Postamendments Devices

- May be initiated by either FDA or Industry
- FDA may, for good cause shown, refer the petition to a device classification panel
- the Panel shall make a recommendation to FDA respecting approval or denial of the petition
Device Classes

A device should be placed in the lowest class whose level of control will provide reasonable assurance of safety and effectiveness

- Class I - General Controls
- Class II – General and Special Controls
- Class III - Premarket Approval
Description of Classes

Class I – Mainly includes devices for which any combination of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of devices
General controls include, for example:

- Prohibition against adulterated or misbranded devices
- Good manufacturing processes (GMPs)
- Registration of manufacturing facilities
- Listing of device types
- Record keeping
- Repair, replacement, refund
- Banned devices
Description of Classes (continued)

Class II

1. Devices which cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such device, and

2. For which there is sufficient information to establish special controls to provide such assurance
Description of Classes (continued)

Special Controls include, for example:

- Performance Standards
- Postmarket Surveillance
- Patient registries
- Development and dissemination of guidelines
- Tracking requirements
- Recommendations and other appropriate actions
Class III

1. Devices for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the S&E of such device, and,
Description of Classes (continued)

2. Such devices are:
   » Life sustaining and/or life supporting,
   » Substantial importance in preventing impairment of human health; or,
   » Present potential or unreasonable risk of illness or injury
Restricted Devices

- Under the provision of Section 520(e) of FD&C Act, the FDA is authorized, by regulation, to restrict the sale, distribution, or use of a device if, because of its potentiality for harmful effect or the collateral measures necessary to its use, FDA determines there cannot otherwise be reasonable assurance of its safety and effectiveness.
Restricted Devices (continued)

- A restricted device can only be sold, distributed, or used either:
  - Upon the oral or written authorization by a licensed practitioner or
  - Under such other conditions specified by regulation

- If the device is restricted to use by persons with specific training or experience in its use or by persons for use in certain facilities, FDA must determine that such a restriction is required for the safe and effective use of the device.
Devices such as cardiac pacemakers and heart valves, for example, require a practitioner’s authorization.

Hearing aids are restricted by a regulation which limits their sale to persons who have obtained a medical evaluation of their hearing loss by a physician within six months prior to the sale of the hearing aid. The labeling of hearing aids must provide information on their use and maintenance.
ECT History & Regulatory Background

LCDR Bradley Cunningham
CDRH/ODE/DONED
ECT History

- Therapeutic application of electricity to the scalp for the purpose of inducing a seizure
- First conducted in 1938, by Cerletti and Bini
- Earliest ECT devices used 125 V 50Hz line-current available from the wall socket modified only by a simple mechanical timing mechanism based upon a metronome...sine wave chosen likely based on convenience\(^1\)
- Originally based on the idea that there is an opposing relationship between seizures and psychoses

ECT History: Development and Use

- 1940s and 1950s
  - Increase in use
  - Lack of alternative treatments
- 1960s – 1980s
  - Decline in use
  - Development of psychopharmacology
  - Reports of misuse and occurrence of adverse events
- 1990 to present
  - Increasing use
  - More than 100,000 US patients receive ECT annually
ECT Development: Technology and Procedure

- **Technology**
  - Changes in waveform
  - Alterations in energy dosing

- **Treatment Procedure**
  - Variations in electrode placement
  - Use of general anesthesia technique
  - Electroencephalographic (EEG) monitoring
ECT Regulation

- Code of Federal Regulations (CFR)
  - 21 CFR §882.5940

- Electroconvulsive therapy device
  
  (a) Identification. An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.
ECT Regulation: “Preamendments” Devices

- Marketed prior to May 28, 1976
- ECT devices are one of the remaining “preamendments” devices
- Class III
- Regulated through premarket notification, 510(k) pathway
ECT Regulation: Application History

- Nine 510(k) applications have been cleared for ECT devices (1984-present)

- Indications for use (IFUs) have included:
  - Depression (unipolar and bipolar)
  - Schizophrenia
  - Bipolar manic (and mixed states)
  - Schizoaffective disorder
  - Schizotypal disorder
  - Catatonia
515(i) Reclassification Process: Safe Medical Devices Act of 1990

- Revise the classification of pre-amendments devices into class I or II

Or

- Require the device to remain class III, and require submission of premarket approval applications (PMAs)
515(i) Reclassification

- FDA’s Federal Register Notices
  - Public Docket: 3045 responses
  - Manufacturers Docket: 2 responses
- Dockets Review
- Manufacturer and User Facility Device Experience (MAUDE) Database Reports
- FDA Literature Review
- Public Panel Meeting
Review Team

- Melissa Burns, LCDR, USPHS: ECT regulatory background, docket
- Peter Como, PhD: Cognitive and memory adverse events review
- Bradley Cunningham, LCDR, USPHS: ECT regulatory background
- Anna Georgiopoulos, MD: Safety and effectiveness review
- Allison Komiyama, PhD: Neuropathology review
- Victor Krauthamer, PhD: ECT regulatory background, electrophysiology
- Cara Krulewitch CNM, PhD, FACNM: Search strategy, Meta-analyses
- Lawrence Park, AM, MD: Lead reviewer
- Jason Schroeder PhD: Effectiveness meta-analysis
- Marjorie Shulman: 510(k) regulatory background
- Federico Soldani MD, SM, PhD: Safety meta-analyses
Goal

- Obtain panel feedback regarding classification of Electroconvulsive Therapy (ECT) devices for each of the currently cleared indications
  - Should ECT devices remain Class III devices and require premarket approval (PMA)?
  - Should ECT devices be reclassified to Class II and require premarket notification (510(k))?