# Neurological Devices Panel Meeting – March 12, 2010

## *Summary*

A meeting of the Neurological Devices Panel was held on March 12, 2010, to discuss and vote on the clinical data presented in the PMA application supplement for approval of the Medtronic Deep Brain Stimulation System for Epilepsy. The Panel heard the Company and FDA presentations, discussed the clinical data presented, addressed the FDA questions, and finally voted (7-5) to recommend that the PMA application for the Medtronic DBS be found "Approvable with Conditions."

## *Device Description*

The implanted system consists of a pulse generator, stimulation leads, and lead extensions. The stimulator is placed in the chest, and the leads are placed stereotactically in the anterior nucleus of the thalamus. The extensions connect the lead to the stimulator.

The clinician programs stimulation parameters using a purpose built programmer; the patient also has a programmer, but has limited ability to change stimulation settings.

With the exception of the patient programmer, all components (both external and implanted) of the system have been previously approved in supplements to the original PMA.

## *Indications for Use*

Bilateral anterior thalamic nucleus stimulation using the Medtronic DBS System for Epilepsy is indicated as adjunctive therapy for reducing the frequency of seizures in individuals diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to antiepileptic medications.

## *VOTE*

The Panel voted (7-5) to recommend that the PMA application supplement for the Medtronic DBS be found "Approvable with Conditions." The panel recommended five conditions of approval:

1. Label changes to include suicidality, depression, memory, anxiety and stimulation related increased seizure frequency
2. Post approval study with a comparator group that assesses the predictive values of subgroups and risk factors for safety issues.
3. Post approval study that is hypothesis-driven
4. Post approval study should have follow-up for up to five years

5. Post approval studies should actively involve psychiatry experts for an appropriate screening tool for suicidality

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