

Summary view of ARTG# 174469

 **ARTG Name:** Medtronic Australasia Pty Ltd - DBS Lead Kit for Deep Brain Stimulation - Model 3391 - Electrode/lead, stimulator, implantable, neurological (174469 Class III)

Sponsor Name: **Medtronic Australasia Pty Ltd - 837**

Therapeutic type: **Medical Device**

Licence product category: **Included**

Class: **Class III**

Active Manufacturers

 **Manufacturer:** Medtronic Inc Active (9913)

Country: **United States Of America**

Step:

No Ceased Manufacturers Located in the Register

Product

 **Product:** DBS Lead Kit for Deep Brain Stimulation - Model 3391 - Electrode/lead, stimulator, implantable, neurological (296264)

Product type: **Procedure Pack**

Intended purpose: The Medtronic Reclaim DBS Therapy is indicated for bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment resistant obsessive-compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

Functional description: The model 3391 DBS Lead is an implantable component of the multiprogrammable system-Reclaim DBS Therapy for OCD and is designed to electrically stimulate specific areas of the brain. The lead features 4.0mm spacing between each of the four 3.0mm electrodes at the distal end. The electrode spread is 24.0mm. Accessories with the lead include straight & short stylet, torque wrench, screening cables, depth stop gauge, burr hole ring & cap, connector boot, tunnelling tool & tips, tubes and lead cap.

Variant information: **Length (cm) 28 - 40**

GMDN: **Neural-tissue electrical stimulation lead (44040)**

File reference:

No Components Located in the Register

Summary view of ARTG# 351630

 **ARTG Name:** Medtronic Australasia Pty Ltd - Percept PC BrainSense B35200 - Brain electrical stimulation system, antitremor (351630 AIMD)
Sponsor Name: Medtronic Australasia Pty Ltd - 837
Therapeutic type: Medical Device
Licence product category: Included
Class: AIMD

Active Manufacturers
 **Manufacturer:** Medtronic Inc Active (9913)
Country: United States Of America
Step:

No Ceased Manufacturers Located in the Register

Product
 **Product:** Percept PC BrainSense B35200 - Brain electrical stimulation system, antitremor (756372)
Product type: Single Device Product
Intended purpose: The Percept PC system is an active implantable device system for deep brain stimulation (DBS) and sensing of bioelectric signals in the brain. Therapy for Movement disorders is indicated for stimulation of the ventral intermediate nucleus (VIM) for patients with disabling essential tremor (ET) or Parkinsonian tremor, or stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for patients with symptoms of Parkinson's disease (PD).
DBS Therapy for movement disorders is also indicated for the stimulation of the internal globus pallidus (Gpi) or the subthalamic nucleus (STN) as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and segmental dystonia, hemidystonia and cervical dystonia (torticollis) for individuals 7 years and older.
Bilateral anterior thalamic nucleus (ANT) stimulation using the Medtronic DBS system for Epilepsy is indicated as adjunctive therapy for reducing the frequency of seizures in adults diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to antiepileptic medications.
Medtronic DBS Therapy is indicated for bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for the treatment of chronic, severe, treatment-resistant OCD in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs)
Functional description: The Medtronic Model B35200 Percept™ PC Neurostimulator with BrainSense™ is part of an active implantable device system for deep brain stimulation and sensing. The DBS system delivers electrical stimulation to targeted regions of the brain to suppress the symptoms associated with a neurologic disorder treatable by brain stimulation.
Variant information: Nil variant (as 1 device) N/A
GMDN: Brain electrical stimulation system, antitremor (37307)

File reference:

No Components Located in the Register