



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	282405	Neurosonica Pty Ltd - Neurosonica SmartSound - Deep brain stimulation therapy management application software
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ARTG entry for	Medical Device Included Class 1
Sponsor	Neurosonica Pty Ltd
Postal Address	220 Daws Road, Daw Park, SA, 5041 Australia
ARTG Start Date	11/11/2016
Product Category	Medical Device Class 1
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Neurosonica Pty Ltd	220 Daws Road Daw Park, SA, 5041 Australia

Products

1. Neurosonica SmartSound - Deep brain stimulation therapy management application software

Product Type	Medical device system	Effective Date	11/11/2016
GMDN	58870 Deep brain stimulation therapy management application software		
Intended Purpose	Neurosonica SmartSound is an audio technology delivered via digital media and with regular use it is intended to assist in management of insomnia, stress and anxiety as well as sleep quality; PMT and headaches as well as hypertension, coronary health and emotional regulation via improving heart rate variability. It may promote optimal work performance by assisting with cognitive response including learning and memory; depression; ADHD; mild pain, and tinnitus. The device may be used by those 18 years or older or teenagers 13-18 years if under adult supervision.		

Specific Conditions

No Specific Conditions included on Record

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