Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	313740	Medtronic Australasia Pty Ltd - Enlite Glucose Sensor - Subcutaneous glucose sensor

ARTG entry for	Medical Device Included Class III
Sponsor	Medtronic Australasia Pty Ltd
Postal Address	PO Box 945, NORTH RYDE BC, NSW, 1670 Australia
ARTG Start Date	29/01/2019
Product Category	Medical Device Class III
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
Medtronic Minimed	18000 Devonshire Street Northridge, California, 91325 United States Of America

Products

1 . Enlite Glucose Sensor - Subcutaneous glucose sensor

Product Type	Single Device Product	**Effective Date**	29/01/2019

GMDN	59016 Subcutaneous glucose sensor
Functional Description	The Enlite glucose sensor continuously converts tiny amounts of glucose from the interstitial fluid under your skin into an electronic signal. Medtronic continuous glucose monitoring systems then use these signals to provide sensor glucose values.
Intended Purpose	The Enlite glucose sensor (sensor) is indicated for use with Medtronic Diabetes (Medtronic) glucose sensing systems to continuously monitor glucose levels in persons age 7 or older with type 1 diabetes. The sensor is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor may be used as part of a system with Guardian Connect and with iPro 2 (MMT-7745). The sensor may also be used as part of a system with the Paradigm Veo (MMT-554/MMT-754) and MiniMed 640G insulin pumps. The insulin pump system can use the sensor glucose values as an input to automatically suspend insulin delivery. The indication for children ages 7 through 17 is limited to those who are supervised by a caregiver. The caregiver must be at least 18 years of age.
Variant information	Quantity/pack MMT-7008 - 1 pack Quantity/pack MMT-7008 - 5 pack

Specific Conditions

1. The person in relation to whom the kind of medical device (the Device) is included in the ARTG (the sponsor) must provide to the Therapeutic Goods Administration, Department of Health, reports that meet the following requirements: · The report must contain all available postmarket data including sales numbers and events and complaints reporting relevant to the Device, including when the Device is supplied for use for paediatric patients aged 7 to 17 years of age. · The data must be collated from all available sources, including but not limited to: registries in the countries where the Device has been supplied (if available), reports of any events (not only adverse events) and complaints, and technical and/or clinical literature, including details and interim and/or final outcomes of any study and/or trial relevant to the Device. · The report also must include a thorough and critical written analysis of the information specified in the point above, including analysis of whether the Device has been performing as intended and whether any safety concerns have been identified. · The report must describe the search strategy and methodology that demonstrate that all relevant postmarket data has been included, and make conclusions, based on the sound arguments about the performance of the Device. · If the Device has not been supplied in Australia or in other countries within the period covered by the report, or if post market data for the device has not been received by the sponsor within the period covered by the report, the report must state this and explain the reasons for not supply. 2. The information must be provided on a six monthly basis, by no later than 1 April and 1 October each year. The reports due 1 April will cover data from 1 September of the previous year to 28 February (29 Feb for leap years) of the current year, and the reports due 1 October will contain data from 1 March to 31 August of the current year. The first report is due no later than 1 October 2019, and the sixth report is to be submitted by 1 April 2022. 3. The updated IFU must be provided to the TGA within 3 months and no later than 29 April 2019. 4. The above mentioned information must be provided at the following email address: postmarketdevices@health.gov.au (or any other address if notified by the TGA).

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