Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 2) 2024

I, Tracey Duffy, as delegate of the Secretary of the Department of Health and Aged Care, make the following determination.

Dated 16 October 2024

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 2) 2024*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 41FDB(7) of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018

1 Before subsection 5(7)

Insert:

Class III medical devices

2 Paragraph 5(7)(a)

Omit "Division 1 of".

3 Part 2 of Schedule 1 (cell at table item 8, column 4)

Before "either", insert "for medical devices that are not exempted, by the United States Food and Drug Administration, from section 510(k) requirements—".

4 Part 4 of Schedule 1 (cell at table item 11, column 4)

Repeal the cell, substitute:

one of the following:

(a) a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act;

(b) an order approving an application for premarket approval under section 515 of the US FDC Act