

## NOTICE OF FILING AND HEARING

This document was lodged electronically in the FEDERAL COURT OF AUSTRALIA (FCA) on 1/09/2021 11:07:47 AM AEST and has been accepted for filing under the Court's Rules. Filing and hearing details follow and important additional information about these are set out below.

### Filing and Hearing Details

Document Lodged:	Originating Application - Form 15 - Rule 8.01(1)
File Number:	NSD883/2021
File Title:	SECRETARY OF THE DEPARTMENT OF HEALTH v MEDTRONIC AUSTRALASIA PTY LTD ACN 001 162 661
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	To Be Advised
Time and date for hearing:	To Be Advised
Place:	To Be Advised



A handwritten signature in blue ink that reads 'Sia Lagos'.

Dated: 1/09/2021 1:04:05 PM AEST

Registrar

### Important Information

As required by the Court's Rules, this Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The Reason for Listing shown above is descriptive and does not limit the issues that might be dealt with, or the orders that might be made, at the hearing.

The date and time of lodgment also shown above are the date and time that the document was received by the Court. Under the Court's Rules the date of filing of the document is the day it was lodged (if that is a business day for the Registry which accepts it and the document was received by 4.30 pm local time at that Registry) or otherwise the next working day for that Registry.



Form 15  
Rules 8.01(1), 8.04(1)

**ORIGINATING APPLICATION**

**FEDERAL COURT OF AUSTRALIA  
DISTRICT REGISTRY: NEW SOUTH WALES  
DIVISION: GENERAL**

**NO NSD 883 OF 2021**

**SECRETARY OF THE DEPARTMENT OF HEALTH**

Applicant

**MEDTRONIC AUSTRALASIA PTY LTD (ACN 001 162 661)**

Respondent

To the Respondent

The Applicant applies for the relief set out in this application.

The Court will hear this application, or make orders for the conduct of the proceeding, at the time and place stated below. If you or your lawyer do not attend, then the Court may make orders in your absence.

You must file a notice of address for service (Form 10) in the Registry before attending Court or taking any other steps in the proceeding.

**TIME AND DATE FOR HEARING:**

**PLACE:**

Date:

.....  
Signed by an officer acting with  
the authority of the District Registrar

**DETAILS OF CLAIM**

On the grounds stated in the statement of claim, accompanying affidavit or other document prescribed by the rules the Applicant claims:

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Filed on behalf of the Applicant, Secretary of the Department of Health

File ref: 20207701

Prepared by: Sonja Marsic  
AGS lawyer within the meaning of s 551 of the *Judiciary Act 1903*

Address for Service:  
The Australian Government Solicitor,  
Level 42, 25 Martin Place, Sydney, NSW 2000  
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Sonja.Marsic@ags.gov.au  
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## Declarations

1. Declarations pursuant to s 21 of the *Federal Court of Australia Act 1976* (Cth) that:
  - 1.1. During the period 1 September 2015 to 31 January 2020 (**Relevant Period**), on each occasion that Medtronic Australasia Pty Ltd (**Medtronic**) supplied the 'Infuse Bone Graft' (**Kit**) not in conjunction with the 'LT Cage' (**Cage**), Medtronic contravened s 19D(1) of the *Therapeutic Goods Act 1989* (Cth) (as in force during the Relevant Period) (**Act**) by supplying in Australia a therapeutic good for use in humans in circumstances where:
    - 1.1.1. the good was not registered or listed goods in relation to Medtronic for the purpose of s 19D(1)(b)(i); and
    - 1.1.2. the matters in s 19D(1)(b)(ii)-(iv) did not apply.
  - 1.2. In the alternative to 1.1 above, during the Relevant Period, on each occasion that Medtronic supplied the Kit not in conjunction with the Cage, Medtronic contravened s 41MIB(1) of the Act by supplying a medical device in Australia in circumstances where:
    - 1.2.1. the device was not of a kind included in the Australian Register of Therapeutic Goods in relation to Medtronic for the purpose of s 41MIB(1)(b)(i); and
    - 1.2.2. the matters in s 41MIB(1)(b)(ia)-(iv) did not apply.

## Pecuniary penalties

2. An order pursuant to s 42Y(2) of the Act that Medtronic pay to the Commonwealth of Australia such pecuniary penalty as the Court determines to be appropriate in respect of each contravention referred to above and pleaded in the Concise Statement.

## Costs

3. An order the Medtronic pay the Applicant's costs of and incidental to these proceedings.

## APPLICANT'S ADDRESS

The Applicant's address for service is:

Australian Government Solicitor,  
Level 42, 25 Martin Place, Sydney, NSW 2000

Email: [Sonja.Marsic@ags.gov.au](mailto:Sonja.Marsic@ags.gov.au)

The Australian Government Solicitor's telephone, facsimile, and document exchange numbers are:

Tel: 02 9581 7505



Fax: 02 9581 7650

The Applicant's address is:

Australian Government Solicitor,  
Level 42, 25 Martin Place, Sydney, NSW 2000

**SERVICE ON THE RESPONDENT**

It is intended to serve this application on all Respondents.

Date: 31 August 2021

A handwritten signature in black ink, appearing to be "Sonja Marsic".

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Sonja Marsic  
AGS lawyer  
for and on behalf of the Australian Government Solicitor  
Lawyer for the Applicant