R16/373727
Document 11

Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Reference: 2016/006464
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[redacted]

Notice under section 9D of the *Therapeutic Goods Act 1989* of decision to vary ARTG inclusions for medical devices

ARTG	GMDN code	Classification
228953	[41670] Radiology picture archiving and communication system application software	Class IIa

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I have decided to vary the Australian Register of Therapeutic Goods (ARTG) under subsection 9D(3D) of the Act following your request on the basis that the information provided for this variation does not indicate any reduction in the quality, safety or performance of the kind of medical devices for the purposes for which these devices are intended to be used.

I have amended the ARTG entry referenced above, as I am satisfied that sufficient evidence of the application of the appropriate conformity assessment procedures to the kinds of medical devices has been provided to the TGA.

Therefore, I have varied the following information:

- Name and site address of the manufacturer

  To: Varian Medical Systems Inc at 3100 Hansen Way PALO ALTO CA 94304 USA.

Date of amendment: 23 May 2016

For further information on the legislation relevant to these decisions refer:

- *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Details/C2015C00471);
- *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Details/F2016C00150).

The ARTG certificate may be downloaded and printed by logging into the TGA Business Services (TBS) website with your user account (for more information refer http://www.tga.gov.au/tga-business-services).

The TGA will not be issuing a hard-copy of the certificate.

Sponsors' ongoing regulatory responsibilities
Australian sponsors of medical devices have ongoing regulatory responsibilities for the medical devices they supply to the Australian market.

The continued inclusion of the devices of the kind in the ARTG is subject to payment of annual charges.

Ongoing monitoring of quality, safety and performance
Therapeutic goods on the ARTG are subject to ongoing monitoring of their quality, safety and performance. At any time, the ARTG entry may be selected for a review to verify compliance of the goods with the regulatory requirements.

For further information refer the Australian Regulatory Guidelines for Medical Devices (ARGMD) that is available on the TGA website:
http://www.tga.gov.au/industry/devices-argmd.htm

Review of the decision under section 60 of the Act
Should you wish to seek a review of my decision to vary the ARTG entry, your rights of review are outlined in Attachment A to this letter.

Yours sincerely

[redacted] ***(signed electronically)***
Delegate of the Secretary for the purposes of section 9D of the Act
Medical Devices Branch
23 May 2016

Attachment A

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.ley@health.gov.au**' and '**decision.review@tga.gov.au**'

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.