R16/295291
Document 9

RICH, Jane

From: [redacted]
Sent: Thursday, 21 April 2016 1:43 PM
Subject: Device Change Request DV-2016-CR-04504-1 s41JA request. [SEC=UNCLASSIFIED]
Attachments: DCR-s41JA-Notice-Initial Request for Information - DV-2016-CR-04504-1.pdf

Dear [redacted]

After reviewed your Device Change Request DV-2016-CR-04504-1 for ARTG 228953 it has been found that further information is required.
Please refer to the attached section 41JA letter requesting further information.

Regards

[redacted]
Departmental Officer
Devices Application & Verification
Medical Devices Branch
[redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Reference: 2016/006464
(R16/294135)

[redacted]

Email: [redacted]

Attention:

Notice under section 41JA of the *Therapeutic Goods Act 1989* requiring information/documents to be provided

ARTG entry	228953
Device Change Request	DV-2016-CR-04504-1
GMDN[1]:	Radiology picture archiving and communication system application software [41670]

Information is required by no later than close of business 23 May 2016.
I refer to your Device Change Request (DCR) asking to vary the inclusion of the kind of medical device in the Australian Register of Therapeutic Goods (ARTG entry 228953) (the Device).

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 41JA of the *Therapeutic Goods Act 1989* (the Act), I have made a decision to request information in relation to this DCR.

I have made this decision because information provided to the Therapeutic Goods Administration (TGA) in relation to this DCR is not sufficient to decide whether there are sufficient grounds for variation of the ARTG entry under either subsection 9D(1) or 9D(3C) or 9D(3D) of the Act[2].

Important
If you fail to comply with this section 41JA notice and information relating to the Device is not received by the TGA, your DCR may not be successful. Further if information is not

[1] Information as stated in the application
[2] Under section 9D of the Act, in certain circumstances, an ARTG entry may be varied in accordance with the request from the sponsor: if the entry contains information that is incomplete or incorrect (paragraph 9D(1)); if variation would only reduce the class of persons for whom the kind of medical device is suitable; or add a warning, restriction or precaution (paragraph 9D(3D)); and/or if the TGA is satisfied that the variation requested does not indicate any reduction in the quality, safety or performance of the kind of medical device for the purposes for which it is to be used (paragraph 9D(3D))

received by the TGA within a further 10 working days from the day specified in this notice, ARTG entry 228953 may be cancelled[3].

For further information refer to:

- the relevant legislation:
  - *Therapeutic Goods Act 1989* (http://www.legislation.gov.au/Series/C2004A03952); and
  - *Therapeutic Goods (Medical Device) Regulations 2002* (http://www.legislation.gov.au/Series/F2002B00237/Compilations).

Background:

1. On 07 April 2016, the TGA received Device Change Request (DCR) DV-2016-CR-04504-1 requiring variation of the ARTG 228953.
2. The DCR provided the following information:
   - Please update the manufacturer details on the ARTG certificate 228953 as per the Manufacturer Evidence DV-2014-MC-13597-1:; Manufacturer Name: Varian Medical Systems, Inc. ; Manufacturer Address: ; 3100 Hansen Way; Palo Alto; California; 94304 USA; The changes to manufacturer details have already been assessed by TGA. ; This change request is to update the manufacturer details only on the ARTG Certificate. There are no changes to the design of the devices covered under the ARTG entry.

On Review

1. The name of the manufacturer and site address of the manufacturer shown on ARTG 228953 is Velocity Medical Solutions at 1350 Spring Street Suite 275 Atlanta, GA 30309 USA.
2. Manufacturer Evidence DV-2011-MC-13597-1 that supports this ARTG entry accepted a change in the manufacturer name and site address to Varian Medical Systems Inc at 3100 Hansen Way PALO ALTO CA 94304. However after further review of the evidence provided it was found that the letter from manufacturer Velocity Medical Solutions was insufficient in that it was not from the notified body.
3. On 18 April 2016 I spoke to Rachel Tserng concerning the change in the manufacturer name and site address and the lack of evidence from the notified body concerning this change. Therefore I requested further information from the notified body showing that this change is a change in name only and that the quality system remains unchanged.
4. On 18 April 2016 you provided a document titled 'ISO certificate FM 640763 13485:2003' showing the manufacturer as Varian Medical Systems Inc at 1350 Spring Street Suite 275 Atlanta Georgia 30309 USA.
   I note that it states that this certificate is traceable to this company's original registration certificate number CM19.4582 dated January 19, 2011 and issued by NSAI, however I am unable to determine an association with the original EC certificate 252.1087.

Based on the information provided above it has been determined that the document that you have provided is insufficient as it does not provided enough evidence for the Therapeutic Goods Administration (TGA) to be confident that this change in manufacturer name is a change in manufacturer name only and the quality system remains unchanged. This requirement is to prove to the TGA that the change in manufacturer's name is a result of corporate changes only and not: as a result of a new manufacturer taking on responsibility for the production of the devices as an alternate manufacturer to those devices already on the ARTG.

[3] Refer paragraph 41GN(1)(c) of the Act

Therefore, you are requested to provide further information to show that this change in manufacturer's name and site address does not constitute a different manufacturer as defined section 41BE of the Therapeutic Goods Act 1989.

INFORMATION TO BE PROVIDED

You are requested therefore, to provide information listed below within the prescribed timeframe:

- A letter from the notified body that shows that this change in manufacturer name is a change in name only and that the Quality System remains unchanged.

Note: All text must be in English, pictures must be clearly labelled, and text and pictures must be legible.

Timeframe for submitting this information

Regulations 5.2 and 5.6 prescribe that for the purposes of obtaining information that demonstrates that the matters certified under section 41FD were correct in relation to the compliance with the essential principles and application of conformity assessment procedures appropriate to the kind of medical device, and for the purposes of obtaining information that demonstrates that you comply with the conditions applying automatically under paragraphs 41FN(3)(a)(ii) and 41FN(3)(b)(iii) of the Act, the period for obtaining information is 20 working days.

Consistently with these requirements, I request that you provide your response to the address specified further in this Notice by no later than 23 May 2016.

Important

If you fail to comply with this notice and information relating to the Device is not received by the TGA within a further 10 working days from the day specified in this notice (see above), the ARTG entry may be cancelled (subsection 41GN(1)(c) of the Act).

Please ensure that all information required in this notice is provided in your response. The first information received by the TGA will be considered to be the complete and final response to this notice.

You should be aware however, that if information provided is not sufficient to demonstrate compliance of the Device with the relevant regulatory requirements, the Delegate might make a decision to cancel the Device from the ARTG.

Withdraw

You may withdraw your Device Change Request at any time prior to a decision being made whether or not to vary the ARTG. You should note, however, that the fee paid for the Device Change Request is not refundable. If you wish to withdraw your application, you should advise the TGA of this request in writing, via e-mail: devices@tga.gov.au.

How to present the submission

The requested information must be provided as a complete stand-alone submission. Cross-referencing to information submitted to the TGA in support of other ARTG entries or applications still in process may not be acceptable and may not be considered or reviewed.

All requested information must be provided in English. Where material is not originally in English a full translation must be submitted, the accuracy of which is the responsibility of the sponsor.

All text and pictures must be legible, and pictures must be clearly labelled.

If your submission is less than 15 pages, you may email the information to devices@tga.gov.au clearly stating the ARTG number and the application ID in the subject line.

If your submission is longer than 15 pages, it should be sent to:

Devices Applications & Verification Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

The information should be provided in either of the following formats:

a) An electronic copy that contains all of the relevant material (using acceptable digital data storage devices, e.g. in the form of CD or DVD) **(This is the Preferred Method).**
***Note*:** Responses that contain 15 pages or more of the data/information must **not** be sent to the TGA as email attachments. The submitted electronic information must be complete and clearly tabulated and titled.

OR:

b) A single hard copy of the information (two-sided print is acceptable).
- Standard A4 paper must be used for all information (where possible). The margin should be sufficiently large that information is not obscured through binding.
- The information must be supplied in loose-leaf binders. Plastic sleeves or stapled material should be avoided.
- The information must be sectioned for ease of reference, and a table of contents provided which details the content of the binder(s).

Publication of the outcome of the review

For your noting, in the event that the ARTG entry is cancelled, the Secretary is required under section 41GP of the Act to publish particulars of the cancellation as soon as practicable after cancelling the ARTG entry. The information must be published in either the Commonwealth Gazette or on the TGA's website. The TGA's practice is to publish information on its website.

For more information see: https://www.tga.gov.au/compliance-actions-0

Your review rights

Should you wish to seek a review of my decision to require you to provide information/documents about the Device, 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 41JA of the Act
Medical Devices Branch
21 April 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.

RICH, Jane

From: [redacted]
Sent: Thursday, 21 April 2016 5:04 PM
Subject: RE: Device Change Request DV-2016-CR-04504-1 s41JA request. [SEC=UNCLASSIFIED]

Dear [redacted],

Thank you for sending through the request.

We will prepare the response and submit before the due date.

Thanks again [redacted].
Kind regards
[redacted]

[redacted]

From: [redacted]
Sent: Thursday, April 21, 2016 1:43 PM
To: [redacted]
Subject: Device Change Request DV-2016-CR-04504-1 s41JA request. [SEC=UNCLASSIFIED]

Dear [redacted]

After reviewed your Device Change Request DV-2016-CR-04504-1 for ARTG 228953 it has been found that further information is required.
Please refer to the attached section 41JA letter requesting further information.

Regards

[redacted]
Departmental Officer
Devices Application & Verification
Medical Devices Branch
[redacted]

Therapeutic Goods Administration
Department of Health

PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

Register now for the *Medical Devices: how to stay included ~ A TGA workshop about your post-market responsibilities* at Sydney on 19 May, Melbourne 23 June and Brisbane 28 July 2016
