Device Change Request Checklist

Application ID:	DV-2016-CR-04504-1
Submission ID:	DR-2016-01993-1
Registry File:	2016/006464

Sponsor:	Varian Medical Systems Australasia Pty Ltd
ARTG Number:	228953
Classification:	Class IIa

Application Recommendation

Recommendation to amend the ARTG entry: **APPROVE**

Comments:

Reason for Device Change Request
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.

Assessment
The name and site address of the manufacturer shown on the ARTG entry is Velocity Medical Solutions at 1350 Spring Street Suite 275 Atlanta, GA 30309 USA.

Manufacturer Evidence DV-2011-MC-13597-1 was approved however the following issues have been identified:
Version 1 shows that the name of the manufacturer that hold EC Certificate 252.1087 issued by NSAI (notified body) is Velocity Medical Solutions at 1350 Spring Street Suite 275 Atlanta GA 30309

However Version 2 now shows that the name and site address of the manufacturer on EC Certificate CE01414 issued by Bsi (Notified body) is Varian Medical Systems Inc at 3100 Hansen Way PALO ALTO CA 94304.
Attached to this variation is a letter from the old manufacturer Velocity Medical Solutions stating that the Varian Medical Systems Inc has acquired Velocity Medical Solutions.
This evidence was accepted without evidence from the notified body that this change in manufacturer name and site address is a change in manufacturer name and that the quality system remains unchanged.

However, this documentation is insufficient as it does not provide enough evidence for the TGA to be confident that this change in manufacturer name and site address is a change in manufacture name only and that the quality system remains unchanged This requirement is to prove to the TGA that the change in manufacturer's name and/or address is as 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 included on the ARTG

Spoke to the agent [redacted] stating that I need further evidence from the notified body that provides evidence that this is a change in the manufacturer name and that the quality system remains unchanged. (18/04/2016)

Reference/Publication #

Sponsor has provide ISO 13485:2003 showing the manufacturer as Varian Medical Systems Inc at 1350 Spring Street Suite 275 Atlanta Georgia 30309 USA.

However I cannot accept this certificate as it does not provide sufficient information that the change of manufacturer is the same manufacturer as defined under s41BE "kind of medical device"
I note that the site address is the same as the original certificate however there is the issue of a different manufacturer's name.
S41JA request sent

Spoke to Sponsor and they have informed me that they are unable to obtain the requested document from the notified body to support this change as the notified body has changed.

After review of the information shown above it has been determined that the TGA will allow this change in manufacturer name and site address as the TGA accepted the change in manufacturer name and site address in version 2 DV-2014-MC-13597-1. In addition there is supporting evidence on the internet that states that Varian Medical Systems acquired Velocity Medical Solutions.

No further information is required

Conclusion
Therefore I recommend that the request for the change of manufacturer name and site address shown on ARTG 228953 be approved.

Once approval from the delegate has been provided a 9D request is to be sent to MAG GSU IM Service for amendment.

Assessor: [redacted]

Signature: Signed Electronically **Date:** 23/05/2016

Delegate's Decision: **ENDORSE**

Comments:

Delegate: [redacted]

Signature: Signed electronically **Date:** 23/05/2016

Part 1 – Type of Application

Type of Application		Yes	No	NA
1.1	Medical Device (Included) Changes to device classification, GMDN code, manufacturer, and sponsor cannot be made as this changes the 'kind of medical device'. In these cases the sponsor will need to submit a new device application for a new kind of device.	☑	☐	☐
1.2	Disinfectant (Listing)	☐	☐	☑
1.3	Tampons (Listing)	☐	☐	☑
1.4	Other OTG (Listing)	☐	☐	☑

Part 2 – General Application Details

Application Details		Yes	No	NA
2.1	Is the application a valid device change request? Application submitted in eBS, application fee paid, ARTG entries current, requested change is valid.	☑	☐	☐
2.2	Has the information that was requested been provided? For Listings – request info under s31 For Inclusions – request info under s41JA	☑	☐	☐

Part 3 – Assessment of information provided

Medical Device (Included)		Yes	No	NA
3.1	Is the proposed intended purpose consistent with the manufacturer's intended purpose?	☐	☐	☑
3.2	Do the labels and IFU support the proposed change?	☐	☐	☑
3.3	Was the supporting information sent to clinical for review? All Class III / AIMD devices should be reviewed by Clinical Section before any changes to intended purpose are made.	☐	☐	☑
3.4	If yes to Q3.3, does the submitted clinical data meet the requirements of Schedule 3, part 8 of the Regulations? If it does not meet the requirements then the clinical assessor must provide details of specific deficiencies to explain to the sponsor, and which will form part of a statement of reasons if the application is rejected on these grounds.	☐	☐	☑
3.5	Change of manufacturer? Supported by documentation	Y		
3.6	Are there any more supported claims?			N/A
Disinfectant (Listing)		**Yes**	**No**	**NA**
3.7	Were the initial and proposed labels requested and assessed?	☐	☐	☑
3.8	Do the labels comply with the relevant TGO (TGO 54, 54A, 37)?	☐	☐	☑
3.9	Has the sponsor provided information to support a change in labelling detail claims?	☐	☐	☑

3.10 Has the formulation details been submitted?			
3.11 Does the ARTG entry support the addition of a new product?	☐	☐	☑
3.11 Are there any other requested changes? For example, changes to storage and transport, new sub contractor manufacturer	☐	☐	☑
Tampons (Listing)	**Yes**	**No**	**NA**
3.12 Do labels comply with the relevant TGO (TGO 82; 10.1)?	☐	☐	☑
3.13 Were the test certificates for each batch evaluated against the standards (absorptive capacity; pull strength cord; microbial content)?	☐	☐	☑
3.14 Was the data sent to the labs for evaluation?	☐	☐	☑
3.16 Addition of a new product?	☐	☐	☑
Other OTG (Listing)	**Yes**	**No**	**NA**
3.17 Are the requested changes allowable and appropriate?	☐	☐	☑