

R16/265588



## Device Change Request

Application ID: DV-2016-CR-04504-1  
Status: Under Review  
Date Received: 07/04/2016

---

### Sponsor Details

Agent Name: [REDACTED]  
Sponsor Name: Varian Medical Systems Australasia Pty Ltd  
Contact Name: [REDACTED]  
Email Address: [REDACTED]  
Phone Number: [REDACTED]

---

### Change Request

ARTG No: 228953  
ChangeType: ☐ Variation to ARTG Listed Entry  
☐ Variation to ARTG Registered Entry (High Level)  
☐ Variation to ARTG Registered Entry (IVDs and Disinfectants)  
☒ Variation to ARTG Included Entry

Description: 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.

---

R16/265584



## Work Management

### Task - Change Request Review

Work Process ID: DR-2016-01993-1

Work Process  
Status:

In Progress

Work Process Manager: rci - Queue - New - 2016-04-12

Assigned To:

rci - Queue - New -  
2016-04-12

Applications: Device Change Request: Varian Medical Systems  
Australasia Pty Ltd DV-2016-CR-04504-1 Class: FLAGS:

Default TRIM 2016/006464

Container ID:

#### Task Description

Verify - client details (manufacturer)  
- update CLIENT if necessary  
- address is street not postal  
- Council Directive is correct  
- conformity assessment route is appropriate for device classification  
- certificate schedule(s) present and correct  
- GMDN codes match scope of certificate and schedule(s)  
Inform Applicant to rectify application deficiencies as appropriate

#### Task Information

##### Task Information

Work Process Component: Assessment

Task Status: Active

Planned Start:

11/04/2016

Planned End:

21/06/2016

Actual Start:

12/04/2016

Actual End:

Other tasks' comments:

Management Comment: ARTG 228953 - Radiology picture archiving and communication system application software  
TRIM 2016/006464

Checklist:

☐ Accepted

☐ Rejected

Checklist Comments:

Outcome:

#### Task Specifics

Delegate:

Decision Date: 12/04/2016

Application

DevChangeRequest ARTG No - 228953

Current Decision

-

Reason

-

#### Work Process Summary

---

---

### Clock Information

#### Clock Information

#### [View Stop Clocks](#)

Task Clock Status      Running  
Elapsed TGA Days:      2

Remaining TGA Days:      -2

---

### Supporting Information

#### Letter History:

#### Attached Document History:

No Task Related Documents

---

