R16/373664

Document 10

RICH, Jane

From: [redacted]
Sent: Thursday, 19 May 2016 12:43 PM
Subject: RE: Device Change Request DV-2016-CR-04504-1 s41JA request. [SEC=UNCLASSIFIED]

Importance: High

Dear [redacted],

Thank you for your time over multiple calls and discussion during the preparation of the response to your request.

As discussed, Varian Medical System Inc. purchased velocity Medical Solution in 2014. To change the company name on the ARTG entry, it was first lodged variation to manufacture evidence with Variant EC Certificate (CE01414) and put in change request to change the company name of the ARTG entry 228953 following approval of the manufacture evidence. The company name change was certified by the previous notified body NASI and the letter from the notified body to support this change is difficult to obtain. However, this is only the company name changed and the quality system remain the same.

Thank you[redacted]. Please do not hesitate to let me know if anything further required.

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]

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