RICH, Jane

From:

Sent:

Monday, 18 April 2016 2:56 PM

Subject:

Device Application DV-2016-CR-04504-1 - further supporting document

Attachments:

FM 640763 (SpringStreet).pdf

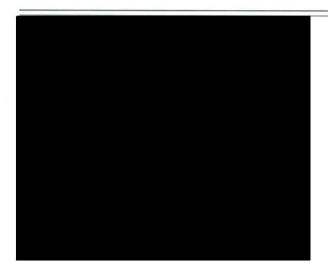
Dear

Thank you for your time over the phone.

The attached is the evidence from the notified body (BSI) of Varian Medical System Inc. to show the linkage for Device Application DV-2016-CR-04504-1.

Thank you Please let me know if you have any questions.

Kind regards



bsi.



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Varian Medical System, Inc.

1350 Spring Street

Suite 275 Atlanta Georgia 30309 USA

Holds Certificate No:

FM 640763

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The Design, Manufacturing, Distribution, Installation, and Service of Medical Imaging Software for Radiation Therapy and Oncology.

This certificate is traceable to this company's original registration certificate number CM19.4582 dated January 19, 2011 and issued by NSAI.

For and on behalf of BSI:

Reg Blake, VP Regulatory Affairs, BSI Group America Inc.

Original Registration Date: 10/05/2015 Effective Date: 10/05/2015 Expiry Date: 01/18/2017



CMDCAS Recognized Registrar



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...making excellence a habit."