

**K041519 MODIFICATION TO: ON-BOARD IMAGER DEVICE**Aug 4, 2004  
58 days to decisionK041519 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k041519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jun 7, 2004
Decision date	Aug 4, 2004
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Varian Medical Systems, Inc.</b>
Location	Palo Alto, CA, US
Contact	VY TRAN
Website	<a href="http://www.varian.com">http://www.varian.com</a>
510(k) history	169 submissions · 169 cleared · 1997-2026

Varian Medical Systems, Inc. is an American radiation oncology company based in Palo Alto, California. The company develops medical devices and software for cancer treatment and radiotherapy. Varian Medical Systems, Inc. has received FDA 510(k) clearances from total submissions since its first clearance in 1997. The company's regulatory portfolio is dominated by Radiology devices, representing 96% of all submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. The company specializes in linear accelerators (LINACs), ra...

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