

**K231317 TrueBeam, TrueBeam STx, Edge, VitalBeam**Sep 12, 2023  
127 days to decisionK231317 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k231317/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	May 8, 2023
Decision date	Sep 12, 2023
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Varian Medical Systems, Inc.</b>
Location	Palo Alto, CA, US
Contact	Peter J. Coronado
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...