FDA 510(k) Premarket Notification

CLEARED

K232870 TrueBeam, TrueBeam STx, EDGE and VitalBeam (4.1)

Dec 21, 2023
97 days to decision

K232870 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k232870/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 15, 2023
Decision date	Dec 21, 2023
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Varian Medical Systems, Inc.**
Location	Palo Alto, CA, US
Contact	Lynn Allman
Website	http://www.varian.com
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...