FDA 510(k) Premarket Notification

CLEARED

K213977 TrueBeam, TrueBeam STx, Edge, VitalBeam

Jun 3, 2022
165 days to decision

K213977 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k213977/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 20, 2021
Decision date	Jun 3, 2022
Days to decision	165 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	Peter J. Coronado
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...