FDA 510(k) Premarket Notification

K162472 TrueBeam-TrueBeam STx-Edge

CLEARED

Jan 19, 2017
135 days to decision

K162472 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k162472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 6, 2016
Decision date	Jan 19, 2017
Days to decision	135 days
Third-party review	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...