FDA 510(k) Premarket Notification

CLEARED

K071992 HIGH-DEFINITION 120 MULTILEAF COLLIMATOR (HD120 MLC)

Aug 15, 2007
26 days to decision

K071992 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k071992/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 20, 2007
Decision date	Aug 15, 2007
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Varian Medical Systems**
Location	Palo Alto, CA, US
Contact	VY TRAN
Website	http://www.varian.com
510(k) history	32 submissions · 32 cleared · 2001-2025

Varian Medical Systems 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 has received FDA 510(k) clearances from total submissions since 2001. The company specializes exclusively in Radiology devices, with its latest clearance in 2025, demonstrating continued regulatory activity and innovation in this field. The company's Radiology portfolio includes linear accelerators, treatment planning systems, applicator sets, and proton therapy syst...