FDA 510(k) Premarket Notification

K030175 2 BASIC

CLEARED

Apr 17, 2003
90 days to decision

K030175 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k030175/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jan 17, 2003
Decision date	Apr 17, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Capintec, Inc.**
Location	Mchenry, IL, US
Contact	MARY ANNE DELL
510(k) history	14 submissions · 14 cleared · 1978-2019