FDA 510(k) Premarket Notification

K122137 CYBERKNIFE ROBOTIC RADIOSURGERY SYSTEM CYBERKNIFE VSI ROBOTIC RADIOSURGERY SYSTEM

CLEARED

Oct 26, 2012
100 days to decision

K122137 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k122137/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 18, 2012
Decision date	Oct 26, 2012
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Accuray Incorporated**
Location	Sunnyvale, CA, US
Contact	ANNE SCHLAGENHAFT
510(k) history	21 submissions · 21 cleared · 2004-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k122137/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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