FDA 510(k) Premarket Notification

K061713 MAGIS1

CLEARED

Jul 21, 2006
32 days to decision

K061713 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k061713/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jun 19, 2006
Decision date	Jul 21, 2006
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary
Other names	MAGIS2

APPLICANT

Company	**Direx Systems Corp.**
Location	Natick, MA, US
Contact	LARISA GERSHTEIN
510(k) history	22 submissions · 22 cleared · 2003-2012