

K061713 MAGIS1Jul 21, 2006
32 days to decisionK061713 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061713/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026