

K102765 PRONEXDec 7, 2010
74 days to decisionK102765 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k102765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 24, 2010
Decision date	Dec 7, 2010
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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