

**K021338 ACCULEAF**Jan 7, 2003  
256 days to decisionK021338 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k021338/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 26, 2002
Decision date	Jan 7, 2003
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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