

K040553 MODIFICATION TO ACCULEAFApr 1, 2004
30 days to decisionK040553 · Product code: IXI · Radiology
Source: <https://www.510kdatabase.net/k040553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Block, Beam-shaping, Radiation Therapy (IXI)
Date received	Mar 2, 2004
Decision date	Apr 1, 2004
Days to decision	30 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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