

K060912 MODIFICATION TO: HI-ART SYSTEMApr 19, 2006
16 days to decisionK060912 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k060912/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 3, 2006
Decision date	Apr 19, 2006
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tomotherapy Incorporated
Location	Madison, WI, US
Contact	KENNETH D BUROKER
510(k) history	6 submissions · 6 cleared · 2003-2011

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