

K033347 MODIFICATION TO: HI-ART SYSTEMNov 12, 2003
23 days to decisionK033347 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k033347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Oct 20, 2003
Decision date	Nov 12, 2003
Days to decision	23 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033347/> 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