

**K013673 HI-ART SYSTEM**Jan 28, 2002  
83 days to decisionK013673 · Product code: **MUJ** · Radiology  
Source: <https://www.510kdatabase.net/k013673/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Nov 6, 2001
Decision date	Jan 28, 2002
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tomo Therapy, Inc.</b>
Location	Middleton, WI, US
Contact	KENNETH D BUROKER
510(k) history	1 submissions · 1 cleared · 2002-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013673/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 19, 2026