

**K083414 RADIONICS XKNIFE HDRT SYSTEM**Mar 2, 2009  
104 days to decisionK083414 · Product code: **MUJ** · Radiology  
Source: <https://www.510kdatabase.net/k083414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Nov 18, 2008
Decision date	Mar 2, 2009
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Integra Radionics, Inc.</b>
Location	Burlington, MA, US
Contact	KEVIN O'CONNELL
510(k) history	10 submissions · 10 cleared · 2006-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083414/> 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 17, 2026