

K041997 RADIONICS XKNIFE RT 3 WITH NON STEREOTACTIC MODULE

Aug 27, 2004
32 days to decision

K041997 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k041997/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Jul 26, 2004
Decision date	Aug 27, 2004
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radionics, A Division of Tyco Healthcare Group LP
Location	Burlington, MA, US
Contact	KEVIN J O'CONNELL
510(k) history	8 submissions · 8 cleared · 2001-2005

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Device record: <https://www.510kdatabase.net/k041997/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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