

**K050963 GAMMACELL 1000 ELITE AND GAMMACELL 3000
ELAN**May 20, 2005
32 days to decisionK050963 · Product code: **MOT** · Radiology
Source: <https://www.510kdatabase.net/k050963/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Irradiator, Blood To Prevent Graft Versus Host Disease (MOT)
Date received	Apr 18, 2005
Decision date	May 20, 2005
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mds Nordion
Location	Ottawa, CA
Contact	ROSS KACHANIWSKY
510(k) history	7 submissions · 7 cleared · 2000-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050963/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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