

K952291 GAMMACELL 3000 ELANAug 25, 1995
101 days to decisionK952291 · Product code: **MOT** · Radiology
Source: <https://www.510kdatabase.net/k952291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Irradiator, Blood To Prevent Graft Versus Host Disease (MOT)
Date received	May 16, 1995
Decision date	Aug 25, 1995
Days to decision	101 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Nordion International, Inc.
Location	Washington, DC, US
Contact	KATHRYN L GLEASON
510(k) history	2 submissions · 2 cleared · 1995-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952291/> 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 20, 2026