FDA 510(k) Premarket Notification

K952291 GAMMACELL 3000 ELAN

CLEARED

Aug 25, 1995
101 days to decision

K952291 · 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