

K837346 MODEL GAMMACELL 1000Jun 24, 1983
100 days to decisionK837346 · Product code: **MOT** · Radiology
Source: <https://www.510kdatabase.net/k837346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Irradiator, Blood To Prevent Graft Versus Host Disease (MOT)
Date received	Mar 16, 1983
Decision date	Jun 24, 1983
Days to decision	100 days
Third-party review	No

APPLICANT

Company	Atomic Energy of Canada
Location	Mchenry, IL, US
510(k) history	6 submissions · 6 cleared · 1977-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k837346/> 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 21, 2026