

K961321 GAMMA GUIDANCE SYSTEMFeb 10, 1997
311 days to decisionK961321 · Product code: **IZD** · Radiology
Source: <https://www.510kdatabase.net/k961321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Uptake, Nuclear (IZD)
Date received	Apr 5, 1996
Decision date	Feb 10, 1997
Days to decision	311 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Radiation Monitoring Devices, Inc.
Location	Watertown, MA, US
Contact	PAUL STOPPEL
510(k) history	2 submissions · 2 cleared · 1997-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961321/> 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 19, 2026