FDA 510(k) Premarket Notification

K961321 GAMMA GUIDANCE SYSTEM

CLEARED

Feb 10, 1997
311 days to decision

K961321 · 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