FDA 510(k) Premarket Notification

K993813 LUMAGEM SCINTILLATION CAMERA

CLEARED

Jan 18, 2000
69 days to decision

K993813 · Product code: **IYX** · Radiology
Source: https://www.510kdatabase.net/k993813/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Scintillation (gamma) (IYX)
Date received	Nov 10, 1999
Decision date	Jan 18, 2000
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gamma Medica**
Location	Northridge, CA, US
Contact	BRADLEY E PATT
510(k) history	1 submissions · 1 cleared · 2000-2000