FDA 510(k) Premarket Notification

K945792 IM512P

K945792 · Product code: **IYX** · Radiology
Source: https://www.510kdatabase.net/k945792/

CLEARED

May 24, 1995
180 days to decision

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Scintillation (gamma) (IYX)
Date received	Nov 25, 1994
Decision date	May 24, 1995
Days to decision	180 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Globus Industries**
Location	Holmdel, NJ, US
Contact	JAMES ZALAYET
510(k) history	1 submissions · 1 cleared · 1995-1995

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k945792/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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