FDA 510(k) Premarket Notification

K011290 PROGNOST ES, MODEL 0302 0000

CLEARED

May 30, 2001
33 days to decision

K011290 · Product code: **IZF** · Radiology
Source: https://www.510kdatabase.net/k011290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Apr 27, 2001
Decision date	May 30, 2001
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Xmar Corp.**
Location	Cleveland Heights, OH, US
Contact	NEIL BARRETT
510(k) history	1 submissions · 1 cleared · 2001-2001