FDA 510(k) Premarket Notification

K013290 MODIFIED 650 MAMMOGRAPHY SYSTEM

CLEARED

Oct 24, 2001
22 days to decision

K013290 · Product code: **IZH** · Radiology
Source: https://www.510kdatabase.net/k013290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mammographic (IZH)
Date received	Oct 2, 2001
Decision date	Oct 24, 2001
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lorad, A Hologic Co.**
Location	Danbury, CT, US
Contact	ROAIDA RIZKALLAH
510(k) history	5 submissions · 5 cleared · 2001-2013