

K013290 MODIFIED 650 MAMMOGRAPHY SYSTEMOct 24, 2001
22 days to decisionK013290 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013290/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026