

K010792 MAMMOGRAPHApr 3, 2001
18 days to decisionK010792 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k010792/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Mar 16, 2001
Decision date	Apr 3, 2001
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Digitec Medical Service Corp.
Location	Lawrenceville, GA, US
Contact	JAMES J MCGINTY
510(k) history	2 submissions · 2 cleared · 1999-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010792/> 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 19, 2026