

**K990192 BIOPSY-DIGIT**Mar 12, 1999  
50 days to decisionK990192 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k990192/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Jan 21, 1999
Decision date	Mar 12, 1999
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sitco, Inc.</b>
Location	Mundelein, IL, US
Contact	ROBERT H MCCARTHY
510(k) history	4 submissions · 4 cleared · 1995-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k990192/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 19, 2026