

**K062039 BIOPSY DIGIT-AM**Sep 11, 2006  
54 days to decisionK062039 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k062039/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Jul 19, 2006
Decision date	Sep 11, 2006
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Giotto USA, LLC</b>
Location	Carmel, IN, US
Contact	Allison Scott
510(k) history	3 submissions · 3 cleared · 2006-2012

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