

**K113607 BIOPSY DIGIT S BIOPSY SL**Aug 10, 2012  
248 days to decisionK113607 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k113607/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Dec 6, 2011
Decision date	Aug 10, 2012
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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