

**K092359 ECHO TIP ULTRA HIGH DEFINITION ULTRASOUND  
ACCESS NEEDLE, MODEL: ECHO-HD-19A**Nov 2, 2009  
90 days to decisionK092359 · Product code: **FCG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k092359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Aug 4, 2009
Decision date	Nov 2, 2009
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Ireland, Ltd.</b>
Location	Limerick, IE
Contact	TRACY MORIARTY
510(k) history	32 submissions · 27 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092359/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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