

**K160229 Echotip Ultra Endobronchial High Definition  
 Ultrasound Needle, Echotip Procore Endobronchial High  
 Definition Ultrasound Biopsy Needle**

Mar 21, 2016  
 49 days to decision

K160229 · Product code: **FCG** · Gastroenterology & Urology  
 Source: <https://www.510kdatabase.net/k160229/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Feb 1, 2016
Decision date	Mar 21, 2016
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Ireland, Ltd.</b>
Location	Limerick, IE
Contact	Lynsey Shine
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/k160229/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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