

**K241209 EchoTip AcuCore™ EUS Biopsy Needle (ECHO-BX-19)**Jul 29, 2024  
90 days to decisionK241209 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k241209/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Apr 30, 2024
Decision date	Jul 29, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Ireland, Ltd.</b>
Location	Limerick, IE
Contact	Brian O'Mara
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/k241209/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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