

**K093195 ECHOTIP ULTRA ENDOBRONCHIAL HIGH DEFINITION
ULTRASOUND NEEDLE, MODEL: ECHO-HD-22-EBUS-O**Jan 21, 2010
104 days to decisionK093195 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k093195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Oct 9, 2009
Decision date	Jan 21, 2010
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Ireland, Ltd.
Location	Limerick, IE
Contact	Jacinta Kilmartin
510(k) history	32 submissions · 27 cleared · 2005-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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