

K261274 EchoTip Ultra® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes

Jul 24, 2026
98 days to decision

K261274 · Product code: FCG · Anesthesiology
Source: <https://www.510kdatabase.net/k261274/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Apr 17, 2026
Decision date	Jul 24, 2026
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary
Other names	EchoTip ProCore® Endobronchial HD Ultrasound Biopsy Needle for Fujifilm Scopes

APPLICANT

Company	Cook Ireland, Ltd.
Location	Limerick, IE
Contact	Caoimhe Murphy
510(k) history	33 submissions · 28 cleared · 2005-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k261274/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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