

K210476 EchoTip Ultra Endoscopic Ultrasound Needle, EchoTip ProCore HD Ultrasound Biopsy Needle, EchoTip Ultra Endobronchial High Definition Ultrasound Needle, EchoTip ProCore Endobronchial High Definition Ultrasound Biopsy Needle

May 20, 2021
90 days to decision

K210476 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k210476/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Feb 19, 2021
Decision date	May 20, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k210476/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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