FDA 510(k) Premarket Notification

CLEARED

K230909 EchoTip® AcuCore™ Ultrasound Biopsy Needle (ECHO-BX-3-22)

May 30, 2023
60 days to decision

K230909 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Mar 31, 2023
Decision date	May 30, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Ireland, Ltd.**
Location	Limerick, IE
Contact	Laura O'Reilly
510(k) history	32 submissions · 27 cleared · 2005-2024

REGULATORY CONSULTANT

Consulting firm	**Cook Medical**
Contact	Paul Meyer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov