FDA 510(k) Premarket Notification

CLEARED

K093195 ECHOTIP ULTRA ENDOBRONCHIAL HIGH DEFINITION ULTASOUND NEEDLE, MODEL: ECHO-HD-22-EBUS-O

Jan 21, 2010
104 days to decision

K093195 · 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