

K182231 Brush Biopsy SetMay 1, 2019
257 days to decisionK182231 · Product code: **FDX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k182231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Cytology Brush (FDX)
Date received	Aug 17, 2018
Decision date	May 1, 2019
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Deflectable Brush Biopsy Set

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Thomas Palmer
510(k) history	175 submissions · 153 cleared · 2006-2024

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