

K191485 Deflectable Brush Biopsy SetJun 26, 2019
22 days to decisionK191485 · Product code: **FDX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Cytology Brush (FDX)
Date received	Jun 4, 2019
Decision date	Jun 26, 2019
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191485/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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