

**K182403 Peel-Away Introducer**May 29, 2019  
267 days to decisionK182403 · Product code: **FED** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k182403/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Sep 4, 2018
Decision date	May 29, 2019
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	Johnathan Liu
510(k) history	175 submissions · 153 cleared · 2006-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182403/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026