

K182520 Flexible OvertubeMay 15, 2019
244 days to decisionK182520 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Sep 13, 2018
Decision date	May 15, 2019
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sumitomo Bakelite Co., Ltd.
Location	Tokyo, JP
Contact	Shiro Agehama
510(k) history	4 submissions · 4 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Mic International Corp.
Contact	Izumi Maruo

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182520/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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