

K160846 AmplifEYEJul 14, 2016
108 days to decisionK160846 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Mar 28, 2016
Decision date	Jul 14, 2016
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medivators, Inc.
Location	Minneapolis, MN, US
Contact	Jeff Kasoff
510(k) history	11 submissions · 11 cleared · 1987-2023

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