

K171208 Trans-anal IntroducerFeb 5, 2018
286 days to decisionK171208 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k171208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Apr 25, 2017
Decision date	Feb 5, 2018
Days to decision	286 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Visionsense, Ltd.
Location	Washington, DC, US
Contact	Alex Chanin
510(k) history	13 submissions · 13 cleared · 2008-2022

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