

K231861 Endoflip™ 300 SystemJul 21, 2023
28 days to decisionK231861 · Product code: **FFX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jun 23, 2023
Decision date	Jul 21, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Viviana Gonzalez
510(k) history	88 submissions · 85 cleared · 2010-2026

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