

K180086 Gyrus ACMI – EZDilate 3-Stage Balloon Dilatation CatheterMar 8, 2018
55 days to decisionK180086 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jan 12, 2018
Decision date	Mar 8, 2018
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Acmi, Inc.
Location	Westborough, MA, US
Contact	Mary Anne Patella
Website	https://www.olympusmedical.com
510(k) history	42 submissions · 42 cleared · 2007-2026

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