

K143609 Gyrus ACMI - EZDilate 3-Stage Balloon Dilatation CatheterMar 27, 2015
98 days to decisionK143609 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k143609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 19, 2014
Decision date	Mar 27, 2015
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Surgical Technologies America
Location	Southborough, MA, US
Contact	MARY ANNE PATELLA
510(k) history	12 submissions · 12 cleared · 2012-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143609/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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