

K103478 SINGLE USE BILIARY DRAINAGE STENT VFeb 24, 2011
90 days to decisionK103478 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k103478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 26, 2010
Decision date	Feb 24, 2011
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corporation
Location	Melville, NY, US
Contact	STACY ABBATIELLO KLUESNER
510(k) history	81 submissions · 81 cleared · 2004-2026

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