

K010107 R STENT BILIARY ENDOPROSTHESISJul 31, 2001
200 days to decisionK010107 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k010107/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jan 12, 2001
Decision date	Jul 31, 2001
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orbus Medical Technologies
Location	Fort Lauderdale, FL, US
Contact	ROBERT FRECHETTE
510(k) history	8 submissions · 0 cleared · 2001-2004

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