

K033212 LIFESTENT SDS BILIARY ENDOPROSTHESISOct 30, 2003
27 days to decisionK033212 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k033212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 3, 2003
Decision date	Oct 30, 2003
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033212/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026