

**K041032 MODIFICATION TO LIFESTENT SDS AND XL SDS  
BILIARY ENDOPROSTHESIS**May 10, 2004  
19 days to decisionK041032 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k041032/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 21, 2004
Decision date	May 10, 2004
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orbus Medical Technologies</b>
Location	Fort Lauderdale, FL, US
Contact	DAVID L CAMP
510(k) history	8 submissions · 0 cleared · 2001-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041032/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026