

**K964119 WALLSTENT TRANSHEPATIC BILIARY  
ENDOPROSTHESIS**Apr 28, 1997  
195 days to decisionK964119 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k964119/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Oct 15, 1996
Decision date	Apr 28, 1997
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Scimed, Inc.</b>
Location	Plymouth, MN, US
Contact	CATHY YOHNK
510(k) history	35 submissions · 26 cleared · 1994-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964119/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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