

K112522 FLEXSTENT BILIARY SELF-EXPANDING STENT SYSTEMDec 30, 2011
121 days to decisionK112522 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k112522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 31, 2011
Decision date	Dec 30, 2011
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Flexible Stenting Solutions, Inc.
Location	Eatontown, NJ, US
Contact	JOSEPH C GRIFFIN III
510(k) history	5 submissions · 0 cleared · 2009-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112522/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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