

K081996 FLEXSTENT BILIARY SELF EXPANDING STENT SYSTEM

Sep 15, 2009
428 days to decision

K081996 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k081996/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 14, 2008
Decision date	Sep 15, 2009
Days to decision	428 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k081996/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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