

K113582 ARCHSTENT BILIARY SYSTEMJun 29, 2012
207 days to decisionK113582 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k113582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 5, 2011
Decision date	Jun 29, 2012
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ostial Corporation
Location	Mountain View, CA, US
Contact	KAITLIN VON HOFFMANN
510(k) history	12 submissions · 11 cleared · 2011-2016

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