

K111315 MULTIPURPOSE DRAINAGE CATHETERJun 8, 2011
29 days to decisionK111315 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k111315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	May 10, 2011
Decision date	Jun 8, 2011
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Navilyst Medical, Inc.
Location	Marlborough, MA, US
Contact	WANDA CARPINELLA
Website	http://www.navilystmedical.com/
510(k) history	35 submissions · 33 cleared · 2009-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111315/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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