

K103353 MULTIPURPOSE DRAINAGE CATHETERJan 14, 2011
59 days to decisionK103353 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k103353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 16, 2010
Decision date	Jan 14, 2011
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary
Other names	NEPHROSTOMY DRAINAGE CATHETER; BILIARY DRAINAGE CATHETER

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

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