

**K111149 HANAROSTENT BILIARY (NNN)**Dec 30, 2011  
249 days to decisionK111149 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k111149/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 25, 2011
Decision date	Dec 30, 2011
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>M.I. Tech Co., Ltd.</b>
Location	Deerfield, IL, US
Contact	PAUL SUMNER
510(k) history	14 submissions · 11 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111149/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026