FDA 510(k) Premarket Notification

K111149 HANAROSTENT BILIARY (NNN)

CLEARED

Dec 30, 2011
249 days to decision

K111149 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k111149/

SUBMISSION DETAILS

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

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