

K183396 HANAROSTENT FASTTM Biliary (NNN)Feb 11, 2019
66 days to decisionK183396 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 7, 2018
Decision date	Feb 11, 2019
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183396/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026