FDA 510(k) Premarket Notification

CLEARED

K202973 HANAROSTENT Benefit Biliary (NNN)

May 11, 2021
223 days to decision

K202973 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k202973/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Sep 30, 2020
Decision date	May 11, 2021
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	**Namsa**
Contact	Kelly Kucharczyk

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202973/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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