

K253327 HANAROSTENT Esophagus Upper (CCC)Oct 30, 2025
30 days to decisionK253327 · Product code: **ESW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k253327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Esophageal (ESW)
Date received	Sep 30, 2025
Decision date	Oct 30, 2025
Days to decision	30 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	Jeongeun Park
510(k) history	14 submissions · 11 cleared · 2008-2025

REGULATORY CONSULTANT

Consulting firm	Namsa
Contact	Monica Montanez

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253327/> 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 14, 2026