

**K200860 HANAROSTENT Esophagus TTS (CCC),
HANAROSTENT Esophagus TTS (NCN)**May 20, 2020
49 days to decisionK200860 · Product code: **ESW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k200860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Apr 1, 2020
Decision date	May 20, 2020
Days to decision	49 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/k200860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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