

**K180180 HANAROSTENT LowAxTM Colon/Rectum (NNN),
HANAROSTENT LowAxTM Duodenum/Pylorus (NNN)**Nov 2, 2018
283 days to decisionK180180 · Product code: **MQR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180180/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Colonic, Metallic, Expandable (MQR)
Date received	Jan 23, 2018
Decision date	Nov 2, 2018
Days to decision	283 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/k180180/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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