

K190141 HANAROSTENT LowAx Colon/Rectum (NNN)Mar 7, 2019
37 days to decisionK190141 · Product code: **MQR** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stent, Colonic, Metallic, Expandable (MQR)
Date received	Jan 29, 2019
Decision date	Mar 7, 2019
Days to decision	37 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

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