FDA 510(k) Premarket Notification

CLEARED

K180180 HANAROSTENT LowAxTM Colon/Rectum (NNN), HANAROSTENT LowAxTM Duodenum/Pylorus (NNN)

Nov 2, 2018
283 days to decision

K180180 · 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