FDA 510(k) Premarket Notification

CLEARED

K183616 HANAROSTENT LowAx Colon/Rectum (NNN), HANAROSTENT LowAx Duodenum/Pylorus (NNN)

Jan 10, 2019
15 days to decision

K183616 · Product code: **MQR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k183616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Colonic, Metallic, Expandable (MQR)
Date received	Dec 26, 2018
Decision date	Jan 10, 2019
Days to decision	15 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