FDA 510(k) Premarket Notification

K223067 Niti-S Duodenal Stent

CLEARED

Jun 14, 2023
264 days to decision

K223067 · Product code: **MUM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k223067/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Metallic, Expandable, Duodenal (MUM)
Date received	Sep 23, 2022
Decision date	Jun 14, 2023
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Niti-S Colonic Comfort Stent

APPLICANT

Company	**Taewoong Medical Co., Ltd.**
Location	Gyeonggi-Do, KR
Contact	Yongjin Kim
510(k) history	15 submissions · 11 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	**MED Institute**
Contact	Daniel J Dillon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov