

K223067 Niti-S Duodenal StentJun 14, 2023
264 days to decisionK223067 · 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](https://accessdata.fda.gov)

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