

**K250663 Niti-S Duodenal Comfort Stent, Niti-S Colonic Comfort Stent**Mar 31, 2025  
26 days to decisionK250663 · Product code: **MUM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k250663/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stent, Metallic, Expandable, Duodenal (MUM)
Date received	Mar 5, 2025
Decision date	Mar 31, 2025
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Taewoong Medical Co., Ltd.</b>
Location	Gyeonggi-Do, KR
Contact	Yongjin "Jeff" Kim
510(k) history	15 submissions · 11 cleared · 2005-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biologics Consulting Group</b>
Contact	Matthew Krueger

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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