

**K243619 Niti-S Esophageal Stent**Oct 30, 2025  
342 days to decisionK243619 · Product code: **ESW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k243619/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Nov 22, 2024
Decision date	Oct 30, 2025
Days to decision	342 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Esophageal TTS Stent

**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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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243619/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026