

K221482 Esophageal TTS StentJun 22, 2022
30 days to decisionK221482 · Product code: **ESW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Esophageal (ESW)
Date received	May 23, 2022
Decision date	Jun 22, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group, Inc.
Contact	Matthew Krueger

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

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