

K223626 Niti-S Biliary Speed D StentMay 26, 2023
172 days to decisionK223626 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k223626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 5, 2022
Decision date	May 26, 2023
Days to decision	172 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](https://accessdata.fda.gov)

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