FDA 510(k) Premarket Notification

K223626 Niti-S Biliary Speed D Stent

CLEARED

May 26, 2023
172 days to decision

K223626 · 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