FDA 510(k) Premarket Notification

CLEARED

K242845 EGIS Biliary Double Bare Stent (BDB080405)

Jun 25, 2025
278 days to decision

K242845 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k242845/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Sep 20, 2024
Decision date	Jun 25, 2025
Days to decision	278 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**S&G Biotech, Inc.**
Location	Yongin-Si, KR
Contact	Yoo Young Ji
510(k) history	2 submissions · 0 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Mtech Group, LLC**
Contact	Dave Kim

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