

K223354 EGIS Biliary Single Bare StentSep 21, 2023
323 days to decisionK223354 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k223354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 2, 2022
Decision date	Sep 21, 2023
Days to decision	323 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	Sung-Kwon Kang
510(k) history	2 submissions · 0 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223354/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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