

K210419 BIOTEQ Drainage Catheter BT-PDS-seriesApr 13, 2022
426 days to decisionK210419 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 11, 2021
Decision date	Apr 13, 2022
Days to decision	426 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioteque Corporation
Location	Taipei City, TW
Contact	Stella Hsu
510(k) history	3 submissions · 3 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210419/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026