

K251019 BIOTEQ Drainage Catheter Set: BT-PD1-SERIES-G and BT-PDS-SERIES-GDec 22, 2025
264 days to decisionK251019 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 2, 2025
Decision date	Dec 22, 2025
Days to decision	264 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

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