

K241444 Biliary Pancreaticobiliary Scope SystemJan 21, 2025
244 days to decisionK241444 · Product code: **FBN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k241444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	May 22, 2024
Decision date	Jan 21, 2025
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen HugeMed Medical Technical Development Co., Ltd.
Location	Shenzhen, CN
Contact	Cathy Shi
510(k) history	7 submissions · 7 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241444/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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