

K251338 Cholangioscope Visualization System (Single-use Video Cholangioscope: SCV-P-01G, SCV-P-02G)Jan 20, 2026
265 days to decisionK251338 · Product code: **FBN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	Apr 30, 2025
Decision date	Jan 20, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Full HD Visualization Endoscopic Image Processor: HDVS-S300A, HDVS-S300B, HDVS-S300C, HDVS-S300D)

APPLICANT

Company	Scivita Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Wu Ruqin
510(k) history	12 submissions · 12 cleared · 2019-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251338/> 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 14, 2026