

K243708 Urology Videoscope System (Single-use Flexible Ureteroscope: SUV-1A-B, SUV-1A-P, SUV-2A-B, SUV-2A-P, SUV-2B-B, SUB-2B-P, SUV-2C-B, SUV-2C-P

Mar 27, 2025
115 days to decision

K243708 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k243708/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Dec 2, 2024
Decision date	Mar 27, 2025
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Single-use Flexible Cystoscope: SUV-1D-B, SUV-1D-P; Endoscopic Image Processor: HDVS-S100A, HDVS-S100D.)

APPLICANT

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