

K241639 Single-use Video Ureterorenoscope (SVU-220US)Jul 1, 2024
24 days to decisionK241639 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k241639/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jun 7, 2024
Decision date	Jul 1, 2024
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Huger Medical Instrument Co., Ltd.
Location	Shanghai, CN
Contact	Shen Junjie
510(k) history	2 submissions · 2 cleared · 2023-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241639/> 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