

K221158 Single-Use Video Flexible Ureterorenoscope SystemMar 6, 2023
319 days to decisionK221158 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k221158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Apr 21, 2022
Decision date	Mar 6, 2023
Days to decision	319 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Red Pine Medical Instrument Co., Ltd.
Location	Guangzhou, CN
Contact	Lifang Zhang
510(k) history	9 submissions · 9 cleared · 2023-2025

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