

K221580 Single-Use Flexible CystoscopeNov 18, 2022
170 days to decisionK221580 · Product code: **FAJ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Jun 1, 2022
Decision date	Nov 18, 2022
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Vathin Medical Instrument Co., Ltd.
Location	Xiangtan, CN
Contact	Du Jing
510(k) history	17 submissions · 17 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221580/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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