

**K231118 Cystoscope System**Nov 13, 2023  
207 days to decisionK231118 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k231118/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Apr 20, 2023
Decision date	Nov 13, 2023
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen HugeMed Medical Technical Development Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Jiang Yuanning
510(k) history	7 submissions · 7 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231118/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026