

**K252598 Flexible Cystoscope (CY50H-20EU, CY50H-20US,  
CY55H-24EU, CY55H-24US)**Sep 15, 2025  
28 days to decision

K252598 · Product code: FAJ · Gastroenterology &amp; Urology

Source: <https://www.510kdatabase.net/k252598/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Aug 18, 2025
Decision date	Sep 15, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shanghai AnQing Medical Instrument Co., Ltd.</b>
Location	Shanghai, CN
Contact	Shuwen Fan
Website	<a href="http://www.anqingmedical.com">http://www.anqingmedical.com</a>
510(k) history	14 submissions · 14 cleared · 2018-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252598/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026