

K252806 Flexible Suction Ureterorenoscope (US27G-12-EU, US27G-12-US, US33G-17-EU, US33G-17-US, US38G-20-EU, US38G-20-US.)

Oct 3, 2025
30 days to decision

K252806 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252806/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Sep 3, 2025
Decision date	Oct 3, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k252806/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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