

K260516 BubbleView Single-Use Digital Flexible Cystoscope
(C38-CS, C38-CRS, C50-C, C50-CR, C50-CB, C50-CBR)

Jul 20, 2026
153 days to decision

K260516 · Product code: FGB · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k260516/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Feb 17, 2026
Decision date	Jul 20, 2026
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	MacroLux Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Ye Linbin
510(k) history	7 submissions · 7 cleared · 2024-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k260516/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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