

K231774 CoralView® Single-use Digital Flexible Ureteroscope (U10)Jan 11, 2024
209 days to decisionK231774 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231774/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jun 16, 2023
Decision date	Jan 11, 2024
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CoralView® Single-use Digital Flexible Ureteroscope (U10-B); CoralView® Single-use Digital Flexible Ureteroscope (U10-BR); CoralView® Single-use Digital Flexible Ureteroscope (U20); CoralView® Single-use Digital Flexible Ureteroscope (U20-B); CoralView® Single-use Digital Flexible Ureteroscope (U20-BR)

APPLICANT

Company	MacroLux Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Linbin Ye
510(k) history	6 submissions · 6 cleared · 2024-2026

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