

**K242699 Flexible Ureteroscope (U-Scope)(2.8/1.2)
(OMI161-2F28-CH12-US)**May 28, 2025
261 days to decisionK242699 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k242699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Sep 9, 2024
Decision date	May 28, 2025
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Flexible Ureteroscope (U-Scope)(2.5/1.2) (OMI161-2F25-CH12-US); Images Systems (Camera-Controlled Unit) (OMI01M12)

APPLICANT

Company	Opcom Medical, Inc.
Location	New Taipei City, TW
Contact	ChingLin Huang
Website	https://www.opcommedical.com/
510(k) history	1 submissions · 1 cleared · 2025-2025

Opcom Medical, Inc. is a subsidiary of OPCOM Group, established in 2022 with a manufacturing facility in New Taipei City, Taiwan. The company specializes in OEM, ODM, and OBM of disposable endoscopes and catheter solutions. OMI provides comprehensive design, R&D, verification, certification, and mass production services backed by over 20 years of industry experience. Opcom Medical has received FDA 510(k) clearance from total submission. The company's regulatory focus is Gastroenterology & Urology devices. The latest clearance was issued in 2025, reflecting active ongoing ...