

K250462 UL UHD-Clear View 4K Camera System (UL-3Chip 4K)Aug 11, 2025
174 days to decisionK250462 · Product code: **FET** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Feb 18, 2025
Decision date	Aug 11, 2025
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Univlabs Technologies Private Limited
Location	Gurugram, IN
Contact	Sunil Kumar Singh
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250462/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026