

**K231760 HP-OCT (HP-OCT)**Mar 8, 2024  
266 days to decisionK231760 · Product code: **HJO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k231760/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biomicroscope, Slit-lamp, Ac-powered (HJO)
Date received	Jun 16, 2023
Decision date	Mar 8, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cylite Pty. , Ltd.</b>
Location	Mulgrave, AU
Contact	Arnold Ouyang
510(k) history	2 submissions · 2 cleared · 2024-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Orasi Consulting</b>
Contact	Lena Sattler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231760/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026