

K160327 ALADDIN HW3.0Oct 5, 2016
243 days to decisionK160327 · Product code: **HJO** · Ophthalmic
Source: <https://www.510kdatabase.net/k160327/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Biomicroscope, Slit-lamp, Ac-powered (HJO) |
| Date received | Feb 5, 2016 |
| Decision date | Oct 5, 2016 |
| Days to decision | 243 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Visia Imaging S.R.L. |
| Location | Ormond Beach, FL, US |
| Contact | Silvia Fantechi |
| 510(k) history | 4 submissions · 4 cleared · 2014-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160327/> 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 27, 2026