

**K150878 ILUMIEN OPTIS**Jul 15, 2015  
105 days to decisionK150878 · Product code: **NQQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k150878/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Traditional   |
| Device classification | System, Imaging, Optical Coherence Tomography (oct) (NQQ) |
| Date received         | Apr 1, 2015   |
| Decision date         | Jul 15, 2015  |
| Days to decision      | 105 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Lightlab Imaging, Inc.</b>           |
| Location       | Rockville, MD, US                       |
| Contact        | ERDIE DE PERALTA                        |
| 510(k) history | 10 submissions · 10 cleared · 2010-2016 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150878/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 2, 2026