

K153634 Wireless Earlens Light Driven Hearing AidApr 6, 2016
110 days to decisionK153634 · Product code: **PLK** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k153634/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tympanic Membrane Direct Contact Hearing Aid (PLK) |
| Date received | Dec 18, 2015 |
| Decision date | Apr 6, 2016 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Earlens Corporation |
| Location | Menlo Park, CA, US |
| Contact | Deborah Arthur |
| 510(k) history | 3 submissions · 2 cleared · 2015-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153634/> 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 June 28, 2026