

K182480 Earlens Contact Hearing AidJan 25, 2019
137 days to decisionK182480 · Product code: **PLK** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k182480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tympanic Membrane Direct Contact Hearing Aid (PLK)
Date received	Sep 10, 2018
Decision date	Jan 25, 2019
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Earlens Corporation
Location	Menlo Park, CA, US
Contact	Judith A. Brimacombe
510(k) history	3 submissions · 2 cleared · 2015-2019

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