

K190540 Ponto 4May 2, 2019
59 days to decisionK190540 · Product code: **LXB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k190540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Mar 4, 2019
Decision date	May 2, 2019
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Oticon Medical AB
Location	Gothenburg, Askim, SE
Contact	Lise Terkelsen
510(k) history	16 submissions · 16 cleared · 2008-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190540/> 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 26, 2026