

K132775 PONTO PLUS AND PONTO PLUS POWERDec 9, 2013
95 days to decisionK132775 · Product code: **LXB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k132775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Sep 5, 2013
Decision date	Dec 9, 2013
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132775/> 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