

**K103594 PONTO PRO POWER**Jun 15, 2011  
189 days to decisionK103594 · Product code: **LXB** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k103594/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Dec 8, 2010
Decision date	Jun 15, 2011
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oticon Medical AB</b>
Location	Gothenburg, Askim, SE
Contact	ULRIKA NIELSEN
510(k) history	16 submissions · 16 cleared · 2008-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103594/> 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 May 26, 2026