

**K211640 Ponto 5 Mini**Aug 10, 2021  
75 days to decisionK211640 · Product code: **LXB** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k211640/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	May 27, 2021
Decision date	Aug 10, 2021
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oticon Medical AB</b>
Location	Gothenburg, Askim, SE
Contact	Anja Ravn
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/k211640/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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