

K161671 Ponto 3, Ponto 3 Power and Ponto 3 SuperPowerSep 29, 2016
105 days to decisionK161671 · Product code: **LXB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k161671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Jun 16, 2016
Decision date	Sep 29, 2016
Days to decision	105 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

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