

**K212136 Cochlear Baha 6 System, Cochlear Baha Fitting Software 6, Cochlear Baha Baha Smart App**Sep 29, 2021  
83 days to decisionK212136 · Product code: **LXB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k212136/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Jul 8, 2021
Decision date	Sep 29, 2021
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cochlear Americas</b>
Location	Englewood, CO, US
Contact	Whitney Alexander
510(k) history	20 submissions · 20 cleared · 2008-2024

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212136/> 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 14, 2026