

**K121317 COCHLEAR BAHA IMPLANT SYSTEM**Oct 12, 2012  
163 days to decisionK121317 · Product code: **MAH** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k121317/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction, Implanted (MAH)
Date received	May 2, 2012
Decision date	Oct 12, 2012
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cochlear Americas</b>
Location	Englewood, CO, US
Contact	SEAN BUNDY
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/k121317/> 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 June 15, 2026