

**K153391 Sophono Bone Conduction Systems (S) Configuration and (M) Configuration**Jun 16, 2016  
205 days to decisionK153391 · Product code: **LXB** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k153391/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Nov 24, 2015
Decision date	Jun 16, 2016
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sophono, Inc.</b>
Location	Lakewood, CO, US
Contact	Rozanne Paciej
510(k) history	5 submissions · 5 cleared · 2010-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153391/> 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 2, 2026