

K100193 OTOMAG BONE CONDUCTION HEARING SYSTEMMay 18, 2010
116 days to decisionK100193 · Product code: **LXB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k100193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Jan 22, 2010
Decision date	May 18, 2010
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sophono, Inc.
Location	Lakewood, CO, US
Contact	Mary Armstrong
510(k) history	5 submissions · 5 cleared · 2010-2016

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