

**K102199 OTOMAG BONE CONDUCTION HEARING SYSTEM
MODEL ALPHA 1 (S) AND ALPHA 1 (M)**May 23, 2011
292 days to decisionK102199 · Product code: **LXB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k102199/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hearing Aid, Bone Conduction (LXB) |
| Date received | Aug 4, 2010 |
| Decision date | May 23, 2011 |
| Days to decision | 292 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102199/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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