

K100649 SOUNDBITE HEARING SYSTEM BY SONITUSJan 14, 2011
312 days to decisionK100649 · Product code: **LXB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k100649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Mar 8, 2010
Decision date	Jan 14, 2011
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sonitus Medical, Inc.
Location	San Carlos, CA, US
Contact	ROBERT J CHIN
510(k) history	2 submissions · 2 cleared · 2011-2011

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