

**K011438 BILATERAL FITTING OF THE BRANEMARK BONE-ANCHORED HEARING AID (BAHA) SYSTEM.**Jul 23, 2001  
74 days to decisionK011438 · Product code: **LXB** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k011438/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	May 10, 2001
Decision date	Jul 23, 2001
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Entific Medical Systems, Inc.</b>
Location	Findley, MN, US
Contact	CONSTANCE BUNDY
510(k) history	5 submissions · 5 cleared · 1999-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011438/> 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 July 4, 2026