

**K100360 BIA300 SERIES IMPLANT AND ABUTMENT, BI300
IMPLANT, BA300 ABUTMENT**Jul 13, 2010
151 days to decisionK100360 · Product code: **LXB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k100360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Feb 12, 2010
Decision date	Jul 13, 2010
Days to decision	151 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cochlear Americas
Location	Englewood, CO, US
Contact	SEAN BUNDY
510(k) history	20 submissions · 20 cleared · 2008-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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