

K250215 Baha 7 Sound ProcessorMay 29, 2025
125 days to decisionK250215 · Product code: **LXB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k250215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Jan 24, 2025
Decision date	May 29, 2025
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Baha Fitting Software 7 (P2121898); Baha Smart App (iOS) (P1646054); Baha Smart App (Android) (P1646035); Baha SoundBand

APPLICANT

Company	Cochlear
Location	Centennial, CO, US
Contact	Denis DiMartino
Website	http://www.cochlear.com/
510(k) history	3 submissions · 3 cleared · 2023-2025

Cochlear is a global leader in implantable hearing solutions. The company develops and manufactures cochlear implant systems, bone conduction devices, and complementary accessories. Cochlear operates with a manufacturing facility in Centennial, US, and has helped over 700,000 people restore hearing worldwide. Cochlear has received FDA 510(k) clearances from total submissions since 2023. The company specializes in Ear, Nose, Throat devices, including implantable sound processors and surgical instruments. The latest clearance was in 2025, confirming active regulatory engage...