

K253431 Bone conduction Hearing Aid (BM100, BM300, BM310, SHOKZHEAR BM400, SHOKZ BM400MN, SHOKZHEAR BM410, SHOKZHEAR BM410MN, SHOKZHEAR BM420 and SHOKZHEAR BM420MN)

Aug 19, 2026
322 days to decision

K253431 · Product code: LXB · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k253431/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction (LXB)
Date received	Oct 1, 2025
Decision date	Aug 19, 2026
Days to decision	322 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shokz Health Global Limited
Location	Kowloon, HK
Contact	Guihong Dai
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Contact	Reanny Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)