

**K211350 Bindex BI-2**Apr 29, 2022  
361 days to decisionK211350 · Product code: **MUA** · Radiology  
Source: <https://www.510kdatabase.net/k211350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Sonometer (MUA)
Date received	May 3, 2021
Decision date	Apr 29, 2022
Days to decision	361 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bone Index Finland , Ltd.</b>
Location	Kuopio, FI
Contact	Janne Karjalainen
510(k) history	3 submissions · 3 cleared · 2016-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211350/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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