

**K152020 Bindex BI-100**May 13, 2016  
297 days to decisionK152020 · Product code: **MUA** · Radiology  
Source: <https://www.510kdatabase.net/k152020/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Bone Sonometer (MUA)
Date received	Jul 21, 2015
Decision date	May 13, 2016
Days to decision	297 days
Third-party review	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/k152020/> 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 May 27, 2026