

K161971 Bindex BI-2Jan 9, 2017
175 days to decisionK161971 · Product code: **MUA** · Radiology
Source: <https://www.510kdatabase.net/k161971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Bone Sonometer (MUA)
Date received	Jul 18, 2016
Decision date	Jan 9, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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