

**K200504 BONEBRIDGE System, SAMBA 2 BB, SYMFIT 8.0,  
SAMBA 2 GO, SAMBA 2 Remote**Jul 29, 2020  
149 days to decisionK200504 · Product code: PFO · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k200504/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	Mar 2, 2020
Decision date	Jul 29, 2020
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Med-EI Elektromedizinische Geraete GmbH</b>
Location	Innsbruck, AT
Contact	Carolin Ralser
510(k) history	6 submissions · 5 cleared · 2018-2020

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