

K183373 BonebridgeMar 7, 2019
91 days to decisionK183373 · Product code: **PFO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k183373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	Dec 6, 2018
Decision date	Mar 7, 2019
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Med-EI Elektromedizinische Geraete GmbH
Location	Innsbruck, AT
Contact	Stephanie Haselwanter
510(k) history	6 submissions · 5 cleared · 2018-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183373/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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