

**K201983 BCI 602 Lifts (1 mm), BCI Lifts (1 mm), BCI Lifts (2 mm & 3 mm), BCI Lifts (4 mm)**

Oct 9, 2020  
84 days to decision

K201983 · Product code: PFO · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k201983/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	Jul 17, 2020
Decision date	Oct 9, 2020
Days to decision	84 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	Stephanie Haselwanter
510(k) history	6 submissions · 5 cleared · 2018-2020

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