

**K191457 BONEBRIDGE System, Bone Conduction Implant Kit
(BCI 602 Implant Kit), BCI 602 Sizer Kit, BCI 602 Lifts (1mm)**Sep 18, 2019
110 days to decisionK191457 · Product code: PFO · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k191457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	May 31, 2019
Decision date	Sep 18, 2019
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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