

K240614 Sentio Ti Implant KitJul 10, 2024
127 days to decisionK240614 · Product code: **PFO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k240614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	Mar 5, 2024
Decision date	Jul 10, 2024
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sentio 1 Mini; Genie Medical BAHS

APPLICANT

Company	Oticon Medical AB
Location	Gothenburg, Askim, SE
Contact	Pernilla Gustafsson
510(k) history	16 submissions · 16 cleared · 2008-2024

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