

K203807 Ponto Bone Anchored Hearing System, MONO Surgery KitMar 3, 2021
65 days to decisionK203807 · Product code: **MAH** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k203807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hearing Aid, Bone Conduction, Implanted (MAH)
Date received	Dec 28, 2020
Decision date	Mar 3, 2021
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203807/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026