

K121228 PONTO BONE ANCHORED HEARING SYSTEMSep 7, 2012
137 days to decisionK121228 · Product code: **MAH** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k121228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Bone Conduction, Implanted (MAH)
Date received	Apr 23, 2012
Decision date	Sep 7, 2012
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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