

K092111 ENTOMED SCREENING AUDIOMETER, MODEL SA201,SA202, ENTOMED DIAGNOSTIC AUDIOMETER MODEL SA203,SA204Oct 2, 2009
80 days to decisionK092111 · Product code: **EWO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k092111/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Jul 14, 2009
Decision date	Oct 2, 2009
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Entomed AB
Location	Malmö, SE
Contact	CHARLOTTE MATTISSON
510(k) history	1 submissions · 1 cleared · 2009-2009

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