

**K080955 ZEN PROGRAM (MIND 440 HEARING AID)**Jun 27, 2008  
85 days to decisionK080955 · Product code: **KLW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k080955/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Apr 3, 2008
Decision date	Jun 27, 2008
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Widex Hearing Aid Co., Inc.</b>
Location	Mchenry, IL, US
Contact	FRANCIS KUK
510(k) history	52 submissions · 52 cleared · 1976-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080955/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 25, 2026