

**K130494 UNITRON TINNITUS MASKER FEATURE**May 7, 2013  
70 days to decisionK130494 · Product code: **KLW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k130494/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Masker, Tinnitus (KLW)
Date received	Feb 26, 2013
Decision date	May 7, 2013
Days to decision	70 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Unitron Hearing</b>
Location	Plymouth, MN, US
Contact	JIM REITER
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130494/> 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 9, 2026