

**K011366 CUSTOM TCI-COMBI (TINNITUS CONTROL INSTRUMENT COMBINATION)**

Jun 1, 2001  
28 days to decision

K011366 · Product code: **KLW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k011366/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	May 4, 2001
Decision date	Jun 1, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Hearing Instruments, Inc.</b>
Location	Mchenry, IL, US
Contact	DAVE SLAVIN
510(k) history	42 submissions · 42 cleared · 1984-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k011366/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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