

**K011338 OTO-CEM**Sep 13, 2001  
134 days to decisionK011338 · Product code: **NEA** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k011338/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Ear, Nose And Throat (NEA)
Date received	May 2, 2001
Decision date	Sep 13, 2001
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ototech, Inc.</b>
Location	Washington, DC, US
Contact	MICHAEL G FARROW
510(k) history	1 submissions · 1 cleared · 2001-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011338/> 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 July 5, 2026