

**K171265 Otowave 302 Portable Tympanometer**Jul 28, 2017  
88 days to decisionK171265 · Product code: **NAS** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k171265/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Tympanometer (NAS)                 |
| Date received         | May 1, 2017                        |
| Decision date         | Jul 28, 2017                       |
| Days to decision      | 88 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Amplivox, Ltd.</b>                 |
| Location       | Deer Field, IL, US                    |
| Contact        | Chris Roerig                          |
| 510(k) history | 3 submissions · 3 cleared · 2008-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171265/> 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 1, 2026