

**K003913 HINT AUDIOMETER, OR HINT**Mar 16, 2001  
87 days to decisionK003913 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k003913/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Audiometer (EWO)                   |
| Date received         | Dec 19, 2000                       |
| Decision date         | Mar 16, 2001                       |
| Days to decision      | 87 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Maico-Diagnostics</b>              |
| Location       | Eden Prairie, MN, US                  |
| Contact        | DANIEL EGGAN                          |
| 510(k) history | 3 submissions · 3 cleared · 2001-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003913/> 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 23, 2026