

**K973320 ARTICULATE FITTING SYSTEM**Nov 25, 1997  
83 days to decisionK973320 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k973320/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Audiometer (EWO)                   |
| Date received         | Sep 3, 1997                        |
| Decision date         | Nov 25, 1997                       |
| Days to decision      | 83 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Decibel Instruments, Inc.</b>      |
| Location       | Houston, TX, US                       |
| Contact        | LISA JONES                            |
| 510(k) history | 2 submissions · 2 cleared · 1996-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973320/> 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