

**K043219 AFFINITY (CABINET NAME), AC440, HIT440, OR THE COMBINATION OF SYSTEMS**

Feb 4, 2005  
74 days to decision

K043219 · Product code: **EWO** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k043219/>

**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Audiometer (EWO)                   |
| Date received         | Nov 22, 2004                       |
| Decision date         | Feb 4, 2005                        |
| Days to decision      | 74 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Interacoustics AS</b>              |
| Location       | Minnesota, MN, US                     |
| Contact        | DANIEL EGGAN                          |
| 510(k) history | 4 submissions · 4 cleared · 2005-2009 |

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

Device record: <https://www.510kdatabase.net/k043219/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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