

**K912154 QUALITONE MODEL 48 C-WR-BEHIND THE EAR**Jun 17, 1991  
33 days to decisionK912154 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k912154/>**SUBMISSION DETAILS**

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|                       |                                                 |
|-----------------------|-------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Hearing Aid, Air-conduction, Prescription (ESD) |
| Date received         | May 15, 1991                                    |
| Decision date         | Jun 17, 1991                                    |
| Days to decision      | 33 days                                         |
| Third-party review    | No                                              |
| Summary / Statement   | Summary                                         |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Qualitone</b>                        |
| Location       | Mchenry, IL, US                         |
| Contact        | BRUCE BROWN                             |
| 510(k) history | 39 submissions · 39 cleared · 1976-1996 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912154/> 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 4, 2026