

**K854125 CRAIGWELL AID FITTING SYSTEM AFS**Jan 16, 1986  
99 days to decisionK854125 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k854125/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Audiometer (EWO)                   |
| Date received         | Oct 9, 1985                        |
| Decision date         | Jan 16, 1986                       |
| Days to decision      | 99 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Craigwell Electronics, Ltd.</b>    |
| Location       | Wiltshire Sn2 4bj, GB                 |
| Contact        | WELLBURN                              |
| 510(k) history | 3 submissions · 3 cleared · 1986-1986 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854125/>; 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 6, 2026