

**K221698 Eargo 5 , Eargo 6**Dec 21, 2022  
191 days to decisionK221698 · Product code: **QUH** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k221698/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Traditional   |
| Device classification | Self-fitting Air-conduction Hearing Aid, Over The Counter (QUH) |
| Date received         | Jun 13, 2022  |
| Decision date         | Dec 21, 2022  |
| Days to decision      | 191 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Eargo, Inc.</b>                                |
| Location       | San Jose, CA, US                                  |
| Contact        | Monica Barrett                                    |
| Website        | <a href="http://eargo.com/">http://eargo.com/</a> |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022             |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221698/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026