

**K061459 TRANQUIL TRI-BTE**Jun 30, 2006  
35 days to decisionK061459 · Product code: **KLW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k061459/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Masker, Tinnitus (KLW)             |
| Date received         | May 26, 2006                       |
| Decision date         | Jun 30, 2006                       |
| Days to decision      | 35 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|--|
| Company        | <b>General Hearing Instruments, Inc.</b> |
| Location       | Roanoke, VA, US                          |
| Contact        | ROGER P JUNEAU                           |
| 510(k) history | 5 submissions · 5 cleared · 1985-2006    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061459/> 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 June 30, 2026