

K792214 MODEL TM2-BEHIND-THE-EAR TINNITUSNov 27, 1979
25 days to decisionK792214 · Product code: **BWF** · AnesthesiologySource: <https://www.510kdatabase.net/k792214/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Spirometer, Therapeutic (incentive) (BWF) |
| Date received | Nov 2, 1979 |
| Decision date | Nov 27, 1979 |
| Days to decision | 25 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Starkey Laboratories, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 60 submissions · 60 cleared · 1977-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k792214/>; Data sourced from FDA 510(k) public records (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. - Generated June 15, 2026