

K964426 SMARTOAEFeb 3, 1997
90 days to decisionK964426 · Product code: **EWO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k964426/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Audiometer (EWO) |
| Date received | Nov 5, 1996 |
| Decision date | Feb 3, 1997 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Intelligent Hearing Systems |
| Location | North Miami, FL, US |
| Contact | EDWARD MISKIEL |
| 510(k) history | 13 submissions · 13 cleared · 1991-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964426/> 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 May 31, 2026