

K896401 MICROMATE 304Mar 27, 1990
140 days to decisionK896401 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k896401/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Audiometer (EWO) |
| Date received | Nov 7, 1989 |
| Decision date | Mar 27, 1990 |
| Days to decision | 140 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Madsen North America, Inc. |
| Location | North Tonawanda, NY, US |
| Contact | ZOILA A SEERY |
| 510(k) history | 3 submissions · 3 cleared · 1990-1990 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k896401/>, 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 July 6, 2026