

**K884371 MADSEN IGO-HAT1500 HEARING AID DISPENSER SYSTEM**Feb 13, 1989  
118 days to decisionK884371 · Product code: **ETW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k884371/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Calibrator, Hearing Aid / Earphone And Analysis Systems (ETW) |
| Date received         | Oct 18, 1988  |
| Decision date         | Feb 13, 1989  |
| Days to decision      | 118 days  |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Madsen Electronics (Canada) , Ltd.</b> |
| Location       | Oakville, Ontario, CA                     |
| Contact        | ZOILA SEERY                               |
| 510(k) history | 17 submissions · 17 cleared · 1985-1994   |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884371/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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