FDA 510(k) Premarket Notification

# K833333 IN THE EAR HEARING AID OMNI 100

**CLEARED**

Dec 8, 1983
72 days to decision

K833333 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k833333/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hearing Aid, Air-conduction, Prescription (ESD) |
| Date received | Sep 27, 1983 |
| Decision date | Dec 8, 1983 |
| Days to decision | 72 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Omni Hearing Systems** |
| Location | Mchenry, IL, US |
| 510(k) history | 7 submissions · 7 cleared · 1981-1984 |