

K002897 TITANIUM MIDDLE EAR PROSTHESESOct 11, 2000
23 days to decisionK002897 · Product code: **ETB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k002897/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Partial Ossicular Replacement (ETB) |
| Date received | Sep 18, 2000 |
| Decision date | Oct 11, 2000 |
| Days to decision | 23 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Xomed, Inc. |
| Location | Arnold, MO, US |
| Contact | DAVID TIMLIN |
| 510(k) history | 82 submissions · 81 cleared · 1976-2000 |

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