

**K823912 AUSTIN MODIFIED TOTAL OSSICULAR REPLACE**Jun 24, 1983  
178 days to decisionK823912 · Product code: **ETA** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k823912/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacement, Ossicular Prosthesis, Total (ETA)
Date received	Dec 28, 1982
Decision date	Jun 24, 1983
Days to decision	178 days
Third-party review	No

**APPLICANT**

---

Company	<b>Treace Medical, Inc.</b>
Location	Walker, MI, US
510(k) history	80 submissions · 80 cleared · 1982-1989

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k823912/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 21, 2026