

**K913286 H/A TOTAL-REGULAR, H/A TOTAL-OFFSET**Dec 18, 1991  
147 days to decisionK913286 · Product code: **ETA** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k913286/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacement, Ossicular Prosthesis, Total (ETA)
Date received	Jul 24, 1991
Decision date	Dec 18, 1991
Days to decision	147 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>River Medical, Inc.</b>
Location	Memphis, TN, US
Contact	GEORGE W MURRAY
510(k) history	16 submissions · 13 cleared · 1991-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913286/> 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 July 3, 2026