

**K843461 BIOGLASS OSSICULAR RECONSTRUCTION PROSTH**Jan 9, 1985  
126 days to decisionK843461 · Product code: **ETA** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k843461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacement, Ossicular Prosthesis, Total (ETA)
Date received	Sep 5, 1984
Decision date	Jan 9, 1985
Days to decision	126 days
Third-party review	No

**APPLICANT**

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Company	<b>American Biomaterials Corp.</b>
Location	Princeton, NJ, US
Contact	TODD DERBIN
510(k) history	6 submissions · 6 cleared · 1985-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k843461/>; 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 5, 2026