

**K813224 CERA VITAL CERAMIC EAR CANAL WALL PROSTH**Apr 21, 1982  
163 days to decisionK813224 · Product code: **ESF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k813224/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Composite Synthetic Ptfе With Carbon-fiber, Ent (ESF)
Date received	Nov 9, 1981
Decision date	Apr 21, 1982
Days to decision	163 days
Third-party review	No

**APPLICANT**

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Company	<b>Xomed, Inc.</b>
Location	Arnold, MO, US
510(k) history	82 submissions · 81 cleared · 1976-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k813224/> 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