

**K083621 MEDPOR CUSTOMIZED SURGICAL IMPLANT**Feb 3, 2009  
57 days to decisionK083621 · Product code: **JOF** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k083621/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic, Porous Polyethylene (JOF)
Date received	Dec 8, 2008
Decision date	Feb 3, 2009
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Porex Surgical, Inc.</b>
Location	Fairburn, GA, US
Contact	JERRI L MANN
510(k) history	19 submissions · 19 cleared · 1994-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083621/> 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 June 20, 2026