

**K043133 AOC POROUS POLYETHYLENE, AOC POROUS HDPE,  
AOC POROUS POLYETHYLENE SURGICAL IMPLANT,  
CEREPOR**Mar 2, 2005  
110 days to decisionK043133 · Product code: **KKY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k043133/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Nov 12, 2004
Decision date	Mar 2, 2005
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ceremed , Inc.</b>
Location	Los Angeles, CA, US
Contact	TADEUSZ WELLISZ
510(k) history	20 submissions · 20 cleared · 2004-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043133/> 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 2, 2026