

**K133809 OSTEOFAB PATIENT SPECIFIC FACIAL DEVICE**Jul 28, 2014  
224 days to decisionK133809 · Product code: **KKY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k133809/>**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	Dec 16, 2013
Decision date	Jul 28, 2014
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oxford Performance Materials</b>
Location	South Windsor, CT, US
Contact	LEIGH AYRES
510(k) history	3 submissions · 3 cleared · 2013-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133809/> 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 17, 2026