

**K161052 OsteoFab Patient Specific Facial Device**Jul 20, 2016  
97 days to decisionK161052 · Product code: **KKY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161052/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Apr 14, 2016
Decision date	Jul 20, 2016
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oxford Performance Materials, Inc.</b>
Location	South Windsor, CT, US
Contact	Leigh Ayres
510(k) history	3 submissions · 3 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161052/> 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 28, 2026