

**K172545 SERI Contour**Sep 22, 2017  
30 days to decisionK172545 · Product code: **OXF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172545/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Absorbable, Plastic And Reconstructive Surgery (OXF)
Date received	Aug 23, 2017
Decision date	Sep 22, 2017
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sofregen Medical, Inc.</b>
Location	Medford, MA, US
Contact	Anh Hoang
510(k) history	2 submissions · 2 cleared · 2017-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172545/> 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 25, 2026