

**K200606 O-Genesis Graft Delivery System**May 1, 2020  
53 days to decisionK200606 · Product code: **FMF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200606/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 9, 2020
Decision date	May 1, 2020
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthofix, Inc.</b>
Location	Mckinney, TX, US
Contact	Troy Brooks
510(k) history	57 submissions · 57 cleared · 1996-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200606/> 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 15, 2026