

**K080065 OSFERION**May 2, 2008  
113 days to decisionK080065 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k080065/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jan 10, 2008
Decision date	May 2, 2008
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Terumo Biomaterials Corporation</b>
Location	Center Valley, PA, US
Contact	LAURA STORMS-TYLER
510(k) history	3 submissions · 3 cleared · 2008-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080065/> 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 19, 2026