

**K173424 BioSphere Flex**Sep 12, 2018  
315 days to decisionK173424 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k173424/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Nov 1, 2017
Decision date	Sep 12, 2018
Days to decision	315 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synergy Biomedical</b>
Location	Collegeville, PA, US
Contact	Mark Borden
510(k) history	2 submissions · 2 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173424/> 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 26, 2026