

**K122868 BIOSPHERE BIOACTIVE BONE GRAFT PUTTY**Apr 19, 2013  
213 days to decisionK122868 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k122868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Sep 18, 2012
Decision date	Apr 19, 2013
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synergy Biomedical, LLC</b>
Location	Washington, DC, US
Contact	RANDY PREBULA
510(k) history	2 submissions · 2 cleared · 2013-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122868/> 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 16, 2026