

**K091912 B-GENIN AND R-GENIN**Jun 23, 2010  
363 days to decisionK091912 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k091912/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jun 25, 2009
Decision date	Jun 23, 2010
Days to decision	363 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Berkeley Advanced Biomaterials, Inc.</b>
Location	San Leandro, CA, US
Contact	FRANCOIS GENIN
510(k) history	13 submissions · 13 cleared · 2003-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091912/> 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 18, 2026