

**K180121 Rafugen DBM**Apr 11, 2018  
85 days to decisionK180121 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k180121/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jan 16, 2018
Decision date	Apr 11, 2018
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cellumed Co., Ltd.</b>
Location	Seoul, KR
Contact	JooWoong (Albert) Jang
510(k) history	1 submissions · 1 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180121/> 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