

**K041613 NOVABONE - AR - RESORBABLE BONE GRAFT  
SUBSTITUTE**Aug 25, 2004  
71 days to decisionK041613 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k041613/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jun 15, 2004
Decision date	Aug 25, 2004
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novabone Products, LLC</b>
Location	Alachua, FL, US
Contact	DAVID M GAISSER
Website	<a href="https://novabone.com">https://novabone.com</a>
510(k) history	30 submissions · 30 cleared · 2002-2024

Novabone Products, LLC develops biomaterials for regenerative medicine, specializing in bioactive synthetic bone grafts and osteobiologic products. The company serves dental and orthopedic surgeons with innovative solutions that harness the body's natural healing process. Based in Alachua, Florida, Novabone has been advancing bone graft technology since 2002. The company maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions. All submissions have received clearance, demonstrating consistent regulatory success. Novabone's portfolio span...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k041613/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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