

**K140946 NOVABONE MACROFORM BIOACTIVE PACKABLE,  
NOVABONE MACROFORM BIOACTIVE COMPOSITE**Aug 22, 2014  
130 days to decisionK140946 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k140946/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Apr 14, 2014
Decision date	Aug 22, 2014
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novabone Products, LLC</b>
Location	Alachua, FL, US
Contact	Lisa Simpson
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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