

**K240404 NovaBone Putty - Bioactive Synthetic Bone Graft  
(NB6600, NB6610, NB6615)**Mar 5, 2024  
25 days to decisionK240404 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k240404/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Feb 9, 2024
Decision date	Mar 5, 2024
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novabone Products, LLC</b>
Location	Alachua, FL, US
Contact	Ed Horton
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...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Geyser Medical Consulting</b>
Contact	David Gaisser

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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

Device record: <https://www.510kdatabase.net/k240404/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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