

K110368 NOVABONE PUTTY - BIOACTIVE SYNTHETIC BONE GRAFTApr 14, 2011
65 days to decisionK110368 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k110368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Feb 8, 2011
Decision date	Apr 14, 2011
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Novabone Products, LLC
Location	Alachua, FL, US
Contact	DAVID M GAISSER
Website	https://novabone.com
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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Device record: <https://www.510kdatabase.net/k110368/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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