

**K021336 NOVABONE-RESORBABLE BONE GRAFT
SUBSTITUTE**Jul 25, 2002
90 days to decisionK021336 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k021336/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Apr 26, 2002
Decision date	Jul 25, 2002
Days to decision	90 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/k021336/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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