

K163310 NovaBone IRMJan 18, 2017
56 days to decisionK163310 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k163310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Nov 23, 2016
Decision date	Jan 18, 2017
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Novabone Products, LLC
Location	Alachua, FL, US
Contact	Gregory Pomrink
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...
