

**K152071 NovaBone MacroFORM MIS Composite - 2.5cc,
NovaBone MIS Cartridge Delivery System (cartridge handle
only)**Aug 26, 2015
30 days to decisionK152071 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k152071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jul 27, 2015
Decision date	Aug 26, 2015
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Novabone Products, LLC
Location	Alachua, FL, US
Contact	RICHARD A. DAVIS
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...