FDA 510(k) Premarket Notification

CLEARED

K242299 NovaBone Putty - Synthetic Bioactive Bone Graft

Sep 25, 2024
54 days to decision

K242299 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k242299/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Aug 2, 2024
Decision date	Sep 25, 2024
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Novabone Products, LLC**
Location	Alachua, FL, US
Contact	Ed Horton
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...

REGULATORY CONSULTANT

Consulting firm	**Bruder Consulting & Venture Group**
Contact	Scott Bruder

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