FDA 510(k) Premarket Notification

K082672 NOVABONE PUTTY-BIOACTIVE SYNTHETIC BONE GRAFT

CLEARED

Dec 9, 2008
85 days to decision

K082672 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k082672/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Sep 15, 2008
Decision date	Dec 9, 2008
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Novabone Products, LLC**
Location	Alachua, FL, US
Contact	DAVID M GALSSER
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...