

K100671 NOVABONE DENTAL PUTTY-BIOACTIVE SYNTHETIC BONE GRAFTMar 30, 2010
21 days to decisionK100671 · Product code: **LYC** · Dental
Source: <https://www.510kdatabase.net/k100671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Mar 9, 2010
Decision date	Mar 30, 2010
Days to decision	21 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/k100671/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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