

**K112428 NOVABONE DENTAL MORSELS - BIOACTIVE
SYNTHETIC BONE GRAFT**Dec 16, 2011
115 days to decisionK112428 · Product code: LYC · Dental
Source: <https://www.510kdatabase.net/k112428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Aug 23, 2011
Decision date	Dec 16, 2011
Days to decision	115 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/k112428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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