

K161485 Nanovis Intervertebral Body Fusion System and Forticore(R)

Sep 6, 2016
98 days to decision

K161485 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k161485/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 31, 2016
Decision date	Sep 6, 2016
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nanovis, LLC
Location	San Diego, CA, US
Contact	MATTHEW HEDRICK
510(k) history	10 submissions · 10 cleared · 2011-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161485/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026