

K103297 REDONDO-LJan 27, 2011
80 days to decisionK103297 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k103297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 8, 2010
Decision date	Jan 27, 2011
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seaspine, Inc.
Location	Vista, CA, US
Contact	ETHEL BERNAL
510(k) history	27 submissions · 27 cleared · 2005-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103297/> 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 17, 2026