

K130699 ALEUTIAN SPINAL SYSTEMMay 30, 2013
77 days to decisionK130699 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k130699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 14, 2013
Decision date	May 30, 2013
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	K2m, Inc.
Location	Leesburg, VA, US
Contact	NANCY GIEZEN
510(k) history	100 submissions · 97 cleared · 2007-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130699/> 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 18, 2026