FDA 510(k) Premarket Notification

K113138 ALEUTIAN SYSTEM

CLEARED

Jan 10, 2012
77 days to decision

K113138 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k113138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 25, 2011
Decision date	Jan 10, 2012
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