FDA 510(k) Premarket Notification

K103169 ALEUTTIAN

CLEARED

Mar 7, 2011
131 days to decision

K103169 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k103169/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Oct 27, 2010
Decision date	Mar 7, 2011
Days to decision	131 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