FDA 510(k) Premarket Notification

K162264 Cascadia Interbody System

CLEARED

Sep 21, 2016
41 days to decision

K162264 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k162264/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 11, 2016
Decision date	Sep 21, 2016
Days to decision	41 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