FDA 510(k) Premarket Notification

K161405 Valeo II Interbody Fusion Device System

CLEARED

Aug 19, 2016
91 days to decision

K161405 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k161405/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 20, 2016
Decision date	Aug 19, 2016
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Amedica Corp.**
Location	Salt Lake City, UT, US
Contact	William D. Jordan
510(k) history	16 submissions · 16 cleared · 2002-2018