FDA 510(k) Premarket Notification

K163364 MOJAVE Expandable Interbody System

CLEARED

Mar 15, 2017
105 days to decision

K163364 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k163364/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 30, 2016
Decision date	Mar 15, 2017
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**K2m**
Location	Leesburg, VA, US
Contact	Nancy Giezen
510(k) history	16 submissions · 16 cleared · 2014-2018