FDA 510(k) Premarket Notification

K160699 VIRTU Lumbar Spacer System

CLEARED

Aug 1, 2016
140 days to decision

K160699 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k160699/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 14, 2016
Decision date	Aug 1, 2016
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Met 1 Technologies, LLC**
Location	El Paso, TX, US
Contact	Dan Gerbec
510(k) history	2 submissions · 2 cleared · 2016-2016