FDA 510(k) Premarket Notification

K182210 TiWAVE-L Porous Titanium Lumbar Cage

CLEARED

Jan 7, 2019
145 days to decision

K182210 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k182210/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 15, 2018
Decision date	Jan 7, 2019
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kalitec Medical, LLC**
Location	Orlando, FL, US
Contact	Scott Winn
510(k) history	2 submissions · 2 cleared · 2019-2022