FDA 510(k) Premarket Notification

K181589 Curiteva Lumbar Interbody Fusion System

CLEARED

Dec 20, 2018
185 days to decision

K181589 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181589/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 18, 2018
Decision date	Dec 20, 2018
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Curiteva, LLC**
Location	Tanner, AL, US
Contact	Eric Linder
510(k) history	4 submissions · 4 cleared · 2018-2018