FDA 510(k) Premarket Notification

K181231 DePuy Synthes T-PAL Spacer System

CLEARED

Dec 6, 2018
211 days to decision

K181231 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181231/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 9, 2018
Decision date	Dec 6, 2018
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy Synthes Spine**
Location	Raynham, MA, US
Contact	Heta Shah
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**DePuy Synthes**
Contact	Rozanne Shirley

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov