FDA 510(k) Premarket Notification

CLEARED

K162358 T-PAL Spacer System, T-PAL Titanium Spacer System, SYNFIX Evolution System

Nov 1, 2016
70 days to decision

K162358 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k162358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 23, 2016
Decision date	Nov 1, 2016
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes USA Products, LLC**
Location	West Chester, PA, US
Contact	Eugene Bang
510(k) history	60 submissions · 60 cleared · 2010-2022