

**K162358 T-PAL Spacer System, T-PAL Titanium Spacer System,
SYNFIX Evolution System**Nov 1, 2016
70 days to decisionK162358 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162358/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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