

K100089 SYNTHES T-PAL SPACERMay 13, 2010
121 days to decisionK100089 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k100089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 12, 2010
Decision date	May 13, 2010
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes Spine
Location	Paoli, PA, US
Contact	HEATHER GUERIN
510(k) history	36 submissions · 32 cleared · 1995-2012

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