

K123180 FALCON SPACERJan 8, 2013
90 days to decisionK123180 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k123180/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 10, 2012
Decision date	Jan 8, 2013
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123180/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026