FDA 510(k) Premarket Notification

K123180 FALCON SPACER

CLEARED

Jan 8, 2013
90 days to decision

K123180 · 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