FDA 510(k) Premarket Notification

K130146 SYNTHES SYNFLATE VERTEVRAL BALLOON SYSTEM

CLEARED

May 20, 2013
118 days to decision

K130146 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k130146/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jan 22, 2013
Decision date	May 20, 2013
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes (Usa), LLC**
Location	19380, PA, US
Contact	STACEY BONNELL
510(k) history	7 submissions · 7 cleared · 2010-2018