

K130146 SYNTHES SYNFLATE VERTEVRAL BALLOON SYSTEMMay 20, 2013
118 days to decisionK130146 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130146/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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