FDA 510(k) Premarket Notification

K103320 SYNTHES XRL

CLEARED

Oct 20, 2011
342 days to decision

K103320 · Product code: **MQP** · Orthopedic
Source: https://www.510kdatabase.net/k103320/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Nov 12, 2010
Decision date	Oct 20, 2011
Days to decision	342 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes Spine Co.Lp**
Location	West Chester, PA, US
Contact	HEATHER GUERIN
510(k) history	18 submissions · 18 cleared · 2005-2012