FDA 510(k) Premarket Notification

K133164 DYNESYS TOP-LOADING SPINAL SYSTEM

CLEARED

Jan 16, 2014
91 days to decision

K133164 · Product code: **NQP** · Orthopedic
Source: https://www.510kdatabase.net/k133164/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Metal/polymer Spinal System, Fusion (NQP)
Date received	Oct 17, 2013
Decision date	Jan 16, 2014
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Spine, Inc.**
Location	Minneapolis, MN, US
Contact	MICHELLE LENZ
510(k) history	38 submissions · 35 cleared · 2004-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k133164/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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