FDA 510(k) Premarket Notification

K083118 SPINAL USA ANTERIOR CERVICAL INTERBODY FUSION DEVICE

CLEARED

May 27, 2009
217 days to decision

K083118 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k083118/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Oct 22, 2008
Decision date	May 27, 2009
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal USA**
Location	Brandon, MS, US
Contact	JEFFREY JOHNSON
510(k) history	23 submissions · 23 cleared · 2006-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k083118/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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