FDA 510(k) Premarket Notification

K093015 BINDER INTERVERTEBRAL BODY FUSION DEVICE

CLEARED

Feb 25, 2010
149 days to decision

K093015 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k093015/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 29, 2009
Decision date	Feb 25, 2010
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Binder Biomedical, Inc.**
Location	Boca Raton, FL, US
Contact	LAWRENCE BINDER
510(k) history	2 submissions · 2 cleared · 2010-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k093015/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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