FDA 510(k) Premarket Notification

K082128 DEPUY SPINE LATERAL CAGE SYSTEM

CLEARED

Nov 14, 2008
108 days to decision

K082128 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k082128/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 29, 2008
Decision date	Nov 14, 2008
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy Spine**
Location	Raynham, MA, US
Contact	DENISE DUCHENE
510(k) history	3 submissions · 3 cleared · 2008-2022