FDA 510(k) Premarket Notification

CLEARED

K123207 PRIMALIF TM LLIF UNITARY PEEK LATERAL LUMBAR INTERBODY FUSION SYSTEM

Nov 29, 2012
48 days to decision

K123207 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k123207/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 12, 2012
Decision date	Nov 29, 2012
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osteomed LP**
Location	Addison, TX, US
Contact	PIEDAD PENA
510(k) history	29 submissions · 29 cleared · 2003-2015