FDA 510(k) Premarket Notification

K122872 INTERVERTEBRAL BODY FUSION DEVICE

CLEARED

Feb 28, 2013
162 days to decision

K122872 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k122872/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 19, 2012
Decision date	Feb 28, 2013
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dio Medical Co., Ltd.**
Location	Santa Fe Springs, CA, US
Contact	APRIL LEE
510(k) history	7 submissions · 7 cleared · 2010-2017