FDA 510(k) Premarket Notification

K123388 K7C SPACER

CLEARED

Jan 4, 2013
63 days to decision

K123388 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k123388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 2, 2012
Decision date	Jan 4, 2013
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**K7, LLC**
Location	Chesterland, OH, US
Contact	KARREN E WARDEN, PHD
510(k) history	3 submissions · 3 cleared · 2013-2014