FDA 510(k) Premarket Notification

K133623 C-PLUS

CLEARED

Feb 10, 2014
76 days to decision

K133623 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k133623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 26, 2013
Decision date	Feb 10, 2014
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pioneer Surgical Technology, Inc.**
Location	Marquette, MI, US
Contact	SARAH MCINTYRE
510(k) history	26 submissions · 26 cleared · 2010-2025