FDA 510(k) Premarket Notification

K181963 ostaPek Interbody Fusion Cages

CLEARED

Nov 14, 2018
114 days to decision

K181963 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181963/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 23, 2018
Decision date	Nov 14, 2018
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coligne AG**
Location	Zurich, CH
Contact	Robert Lange
510(k) history	4 submissions · 4 cleared · 2017-2021