FDA 510(k) Premarket Notification

K140331 ORTHALIGN PLUS SYSTEM

CLEARED

Jun 10, 2014
120 days to decision

K140331 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k140331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 10, 2014
Decision date	Jun 10, 2014
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthalign, Inc.**
Location	Newport Beach, CA, US
Contact	DAVID VANCELETTE
510(k) history	13 submissions · 13 cleared · 2009-2024