FDA 510(k) Premarket Notification

K163379 KneeAlign 2 System

CLEARED

Mar 2, 2017
91 days to decision

K163379 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k163379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 1, 2016
Decision date	Mar 2, 2017
Days to decision	91 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k163379/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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