FDA 510(k) Premarket Notification

K091411 KNEEALIGN SYSTEM

CLEARED

Sep 25, 2009
135 days to decision

K091411 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k091411/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 13, 2009
Decision date	Sep 25, 2009
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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