FDA 510(k) Premarket Notification

K242616 Lantern® Hip

CLEARED

Oct 3, 2024
30 days to decision

K242616 · Product code: **ONN** · Orthopedic
Source: https://www.510kdatabase.net/k242616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intraoperative Orthopedic Joint Assessment Aid (ONN)
Date received	Sep 3, 2024
Decision date	Oct 3, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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