FDA 510(k) Premarket Notification

K230463 NSite Scoliosis Assessment App

CLEARED

Nov 15, 2023
267 days to decision

K230463 · Product code: **LDK** · Physical Medicine
Source: https://www.510kdatabase.net/k230463/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Sensing, Optical Contour (LDK)
Date received	Feb 21, 2023
Decision date	Nov 15, 2023
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nsite, Inc.**
Location	Menlo Park, CA, US
Contact	Michael J. Gardner
510(k) history	1 submissions · 1 cleared · 2023-2023