FDA 510(k) Premarket Notification

K181596 Spine Wave Navigated Instruments

CLEARED

Oct 24, 2018
128 days to decision

K181596 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k181596/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 18, 2018
Decision date	Oct 24, 2018
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spine Wave, Inc.**
Location	Shelton, CT, US
Contact	Amy Noccioli
510(k) history	57 submissions · 57 cleared · 2004-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k181596/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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