

**K202184 Practical Navigation Surgical Guidance System
(PNSGS)**Feb 24, 2021
204 days to decisionK202184 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k202184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 4, 2020
Decision date	Feb 24, 2021
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Practical Navigation, LLC
Location	Superior, CO, US
Contact	Brad Clayton
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Phiama, Inc.
Contact	Roger N. White

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202184/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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