

K191012 Navigated Pedicle Access KitAug 7, 2019
113 days to decisionK191012 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k191012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 16, 2019
Decision date	Aug 7, 2019
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Izi Medical Products, LLC
Location	Owings Mills, MD, US
Contact	Qiang Cao
510(k) history	4 submissions · 4 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	7D Surgical, Inc.
Contact	Daniel Ziskind

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

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