

K182721 Choice Spine Navigation SystemJan 8, 2019
102 days to decisionK182721 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k182721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 28, 2018
Decision date	Jan 8, 2019
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Choicespine, LP
Location	Chesterland, OH, US
Contact	Kim Finch
510(k) history	22 submissions · 22 cleared · 2008-2019

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
Contact	Meredith Lee May

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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