

K203115 ARVIS Surgical Navigation SystemJul 14, 2021
271 days to decisionK203115 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k203115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Oct 16, 2020
Decision date	Jul 14, 2021
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Insight Medical Systems, Inc.
Location	Laguna Hills, CA, US
Contact	Nicholas R. van der Walt
510(k) history	2 submissions · 2 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Bob Duffy Associates, Inc.
Contact	Bob Duffy

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

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