

K212028 Dark Star Navigation Instrument SystemSep 27, 2021
90 days to decisionK212028 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k212028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 29, 2021
Decision date	Sep 27, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Republic Spine, LLC
Location	Pompano Beach, FL, US
Contact	James Doulgeris
510(k) history	7 submissions · 7 cleared · 2015-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212028/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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