

K242806 Medyssey Navigation SystemApr 16, 2025
211 days to decisionK242806 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k242806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 17, 2024
Decision date	Apr 16, 2025
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medyssey Co, Ltd.
Location	Santa Fe Springs, CA, US
Contact	Taehyun Park
510(k) history	11 submissions · 11 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	MRC Global
Contact	Christine Scifert

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242806/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026