

**K223108 TELIGEN System Navigation Ready Indications  
(TELIGEN Access Probe, TELIGEN Clear)**Jan 19, 2023  
111 days to decisionK223108 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k223108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 30, 2022
Decision date	Jan 19, 2023
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medos International SARL</b>
Location	Raynham, MA, US
Contact	Karin McDonough
510(k) history	96 submissions · 96 cleared · 2010-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Depuy Spine</b>
Contact	Karin McDonough

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223108/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026