FDA 510(k) Premarket Notification

CLEARED

K223108 TELIGEN System Navigation Ready Indications (TELIGEN Access Probe, TELIGEN Clear)

Jan 19, 2023
111 days to decision

K223108 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k223108/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Depuy Spine**
Contact	Karin McDonough

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