FDA 510(k) Premarket Notification

**CLEARED**

# K241893 CROSSNAV Navigation Enabled Instruments and UNAS Navigation Arrays

Sep 16, 2024
80 days to decision

K241893 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k241893/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Jun 28, 2024 |
| Decision date | Sep 16, 2024 |
| Days to decision | 80 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Synthes GmbH** |
| Contact | Marina Minnock |

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