

K220038 Camber Spine Navigation SystemApr 29, 2022
114 days to decisionK220038 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k220038/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Jan 5, 2022 |
| Decision date | Apr 29, 2022 |
| Days to decision | 114 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Camber Spine Technologies |
| Location | Newtown Square, PA, US |
| Contact | Noel Hetrick |
| 510(k) history | 17 submissions · 17 cleared · 2013-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------------|
| Consulting firm | MRC Global, LLC |
| 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)

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