

**K242121 mBôs (Monogram mBôs TKA System)**Mar 14, 2025  
238 days to decisionK242121 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k242121/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received         | Jul 19, 2024                            |
| Decision date         | Mar 14, 2025                            |
| Days to decision      | 238 days                                |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Monogram Orthopaedics, Inc.</b>    |
| Location       | Austin, TX, US                        |
| Contact        | Patel Nisha                           |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242121/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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