

**K250608 Mako Total Knee Application (3.0)**Apr 25, 2025  
56 days to decisionK250608 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k250608/>**SUBMISSION DETAILS**

---

|                       |                                         |
|-----------------------|-----------------------------------------|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received         | Feb 28, 2025                            |
| Decision date         | Apr 25, 2025                            |
| Days to decision      | 56 days                                 |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |
| Other names           | Hybrid Tip Pointer                      |

**APPLICANT**

---

|                |                                                               |
|----------------|---------------------------------------------------------------|
| Company        | <b>Mako Surgical Corp.</b>                                    |
| Location       | Weston, FL, US                                                |
| Contact        | Shikha Khandelwal                                             |
| Website        | <a href="https://www.stryker.com">https://www.stryker.com</a> |
| 510(k) history | 33 submissions · 33 cleared · 2005-2026                       |

Mako Surgical Corp. is a medical device manufacturer based in Weston, US. Now part of Stryker, the brand continues to operate under the parent company with a focus on robotic-assisted surgical systems. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio. Mako's clearance history spans from 2005 to 2026, demonstrating sustained innovation in joint reconstruction and orthopedic surgery applications. Recent cleared devices include total knee and hip applica...