FDA 510(k) Premarket Notification

# K260222 Mako Total Knee Application

**CLEARED**

Feb 25, 2026
30 days to decision

K260222 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k260222/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Jan 26, 2026 |
| Decision date | Feb 25, 2026 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Mako Surgical Corp.** |
| Location | Weston, FL, US |
| Contact | Rita Koremblum |
| Website | https://www.stryker.com |
| 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...