

**K243751 Mako Total Hip Application 5.0**Mar 5, 2025  
90 days to decisionK243751 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k243751/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 5, 2024
Decision date	Mar 5, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mako Surgical Corp.</b>
Location	Weston, FL, US
Contact	Rita Koremblum
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...