

**K170581 Mako Total Knee Application**May 11, 2017  
72 days to decisionK170581 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k170581/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 28, 2017
Decision date	May 11, 2017
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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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...

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