

K241011 Mako Total Knee Application

Jun 11, 2024
60 days to decisionK241011 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k241011/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 12, 2024
Decision date	Jun 11, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mako Surgical Corp.
Location	Weston, FL, US
Contact	Edwards Anne
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...