

K193128 Mako Total Hip ApplicationFeb 2, 2020
82 days to decisionK193128 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k193128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 12, 2019
Decision date	Feb 2, 2020
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mako Surgical Corp.
Location	Weston, FL, US
Contact	Liza Gordillo
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...
