FDA 510(k) Premarket Notification

CLEARED

K191998 Mako Total Hip Application, Mako Total Knee Application

Sep 24, 2019
60 days to decision

K191998 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k191998/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 26, 2019
Decision date	Sep 24, 2019
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mako Surgical Corp.**
Location	Weston, FL, US
Contact	Shikha Khandelwal
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...