FDA 510(k) Premarket Notification

CLEARED

K080368 MAKO SURGICAL CORP. UNICONDYLAR KNEE IMPLANT SYSTEM II

Jun 20, 2008
129 days to decision

K080368 · Product code: **HSX** · Orthopedic
Source: https://www.510kdatabase.net/k080368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Feb 12, 2008
Decision date	Jun 20, 2008
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mako Surgical Corp.**
Location	Weston, FL, US
Contact	WILLIAM F TAPIA
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...