

K193135 TSolution One Total Knee ApplicationDec 11, 2019
29 days to decisionK193135 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k193135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 12, 2019
Decision date	Dec 11, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	THINK Surgical, Inc.
Location	Fremont, CA, US
Contact	Meliha Mulalic
Website	https://www.thinksurgical.com
510(k) history	22 submissions · 22 cleared · 2015-2026

THINK Surgical, Inc. is an innovator in orthopedic surgical robotics based in Fremont, California. The company develops miniature robotic systems that assist surgeons in performing joint replacement procedures. THINK Surgical has received FDA 510(k) clearances from total submissions since 2015. Orthopedic devices represent 86% of the company's regulatory portfolio. The company remains active, with its latest clearance in 2026. The company's core offering is the TMINI® Miniature Robotic System, a wireless robotic platform designed for total knee replacement. THINK Surgical...