

K201255 TSolution® One Total Knee ApplicationJun 10, 2020
30 days to decisionK201255 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k201255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 11, 2020
Decision date	Jun 10, 2020
Days to decision	30 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...