

**K191369 TSolution One Total Knee Application**Oct 8, 2019  
139 days to decisionK191369 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k191369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	May 22, 2019
Decision date	Oct 8, 2019
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>THINK Surgical, Inc.</b>
Location	Fremont, CA, US
Contact	Meliha Mulalic
Website	<a href="https://www.thinksurgical.com">https://www.thinksurgical.com</a>
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...

**CLINICAL EVIDENCE - NCT03017261****TSolution One® Total Knee Arthroplasty**

Status	Completed
Enrollment	115 patients (actual)
Study sites	6 sites
Condition studied	Osteoarthritis, Knee
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 26, 2019
Sponsor	Think Surgical Inc. (Industry)

**Primary outcome**

Percentage of Patients With Postoperative Coronal Limb Alignment More Than  $\pm 3$  Deg From the Planned Coronal Limb Alignment

**Secondary outcome**

Percentage of Patients Experiencing a Composite of Relevant Safety Adverse Events

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT03017261](https://clinicaltrials.gov/study/NCT03017261)