

**K243481 TMINI Miniature Robotic System**Jan 6, 2025  
59 days to decisionK243481 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k243481/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 8, 2024
Decision date	Jan 6, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>THINK Surgical, Inc.</b>
Location	Fremont, CA, US
Contact	Denise Duchene
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...