

K261024 TMINI Miniature Robotic System

Jul 24, 2026
116 days to decision

K261024 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k261024/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Mar 30, 2026
Decision date	Jul 24, 2026
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	THINK Surgical, Inc.
Location	Fremont, CA, US
Contact	Denise Duchene
Website	https://www.thinksurgical.com
510(k) history	23 submissions · 23 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...