

K262121 Ion-L Navigated Instruments

Jul 24, 2026
31 days to decision

K262121 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k262121/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 23, 2026
Decision date	Jul 24, 2026
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	SurGenTec, LLC
Location	Boca Raton, FL, US
Contact	Richard Sharp
Website	https://www.surgentec.com
510(k) history	26 submissions · 26 cleared · 2017-2026

SurGenTec, LLC is a medical device manufacturer specializing in orthopedic surgical solutions. The company operates with a manufacturing facility in Boca Raton, US. SurGenTec has received FDA 510(k) clearances from total submissions since its first clearance in 2017. Orthopedic devices represent 78% of the company’s regulatory portfolio. The company remains actively engaged in FDA 510(k) submissions, with its most recent clearance in 2026. SurGenTec’s product portfolio includes fusion systems, graft delivery instruments, bone void fillers, and specialized surgical navigat...