

K260329 Ion-C Navigation InstrumentsMay 22, 2026
112 days to decisionK260329 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k260329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 30, 2026
Decision date	May 22, 2026
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SurGenTec, LLC
Location	Boca Raton, FL, US
Contact	Richard Sharp
Website	https://www.surgentec.com
510(k) history	24 submissions · 24 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...