

**K261209 Ion-L**Jun 11, 2026  
59 days to decisionK261209 · Product code: **MRW** · Orthopedic  
Source: <https://www.510kdatabase.net/k261209/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Apr 13, 2026
Decision date	Jun 11, 2026
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SurGenTec, LLC</b>
Location	Boca Raton, FL, US
Contact	Richard Sharp
Website	<a href="https://www.surgentec.com">https://www.surgentec.com</a>
510(k) history	25 submissions · 25 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...

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