

**K240086 Ion 3D**Feb 8, 2024  
28 days to decisionK240086 · Product code: **MRW** · Orthopedic  
Source: <https://www.510kdatabase.net/k240086/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Jan 11, 2024
Decision date	Feb 8, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SurGenTec, LLC</b>
Location	Boca Raton, FL, US
Contact	Guilherme Pires
Website	<a href="https://www.surgentec.com">https://www.surgentec.com</a>
510(k) history	23 submissions · 23 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...