

**K211855 Ion Facet Screw System**Feb 25, 2022  
254 days to decisionK211855 · Product code: **MRW** · Orthopedic  
Source: <https://www.510kdatabase.net/k211855/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Jun 16, 2021
Decision date	Feb 25, 2022
Days to decision	254 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	Andrew Shoup
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k211855/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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