

**K211628 MIS Precision Chevron Bunion System**Jan 31, 2022  
249 days to decisionK211628 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k211628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 27, 2021
Decision date	Jan 31, 2022
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Relja Innovations, LLC</b>
Location	Brookfield, WI, US
Contact	David Pancratz
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Acknowledge Regulatory Strategies, Inc.</b>
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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