

**K213615 Shoulder Innovations Total Shoulder System**Mar 11, 2022  
116 days to decisionK213615 · Product code: **PKC** · Orthopedic  
Source: <https://www.510kdatabase.net/k213615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-constrained (PKC)
Date received	Nov 15, 2021
Decision date	Mar 11, 2022
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shoulder Innovations, Inc.</b>
Location	Holland, MI, US
Contact	Don Running
510(k) history	8 submissions · 8 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213615/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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