

**K203108 Ignite Stemless Anatomic Shoulder System**Jul 16, 2021  
274 days to decisionK203108 · Product code: **PKC** · Orthopedic  
Source: <https://www.510kdatabase.net/k203108/>**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	Oct 15, 2020
Decision date	Jul 16, 2021
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ignite Orthopedics, LLC</b>
Location	Winona Lake, IN, US
Contact	Matt Purdy
510(k) history	2 submissions · 2 cleared · 2021-2021

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