

**K201072 Ensemble CMC, Size 141, Ensemble CMC, Size 151,  
Ensemble CMC, Size 161**Dec 2, 2020  
224 days to decisionK201072 · Product code: KYI · Orthopedic  
Source: <https://www.510kdatabase.net/k201072/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Wrist, Carpal Trapezium (KYI)
Date received	Apr 22, 2020
Decision date	Dec 2, 2020
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ensemble Orthopedics, LLC</b>
Location	Austin, TX, US
Contact	Sandie Roth
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201072/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 20, 2026