

**K222278 LOSPA TKR System Instrumentation, EXULT TKR System Instrumentation**Aug 26, 2022  
28 days to decisionK222278 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k222278/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jul 29, 2022
Decision date	Aug 26, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Corentec Co., Ltd.</b>
Location	West Cadwell, NJ, US
Contact	Yoorim Bae
510(k) history	33 submissions · 33 cleared · 2010-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222278/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026