

**K190543 Cannulated Hemi Implant**May 31, 2019  
88 days to decisionK190543 · Product code: **KWD** · Orthopedic  
Source: <https://www.510kdatabase.net/k190543/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	Mar 4, 2019
Decision date	May 31, 2019
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vilex IN Tennessee, Inc.</b>
Location	Lakewood Ranch, FL, US
Contact	Sylvia Southard
510(k) history	7 submissions · 7 cleared · 2014-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190543/> 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 28, 2026