

**K190100 USTAR II System**Sep 23, 2019  
244 days to decisionK190100 · Product code: **KRO** · Orthopedic  
Source: <https://www.510kdatabase.net/k190100/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Jan 22, 2019
Decision date	Sep 23, 2019
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>United Orthopedic Corporation</b>
Location	Hsinchu, TW
Contact	Lois Ho
510(k) history	40 submissions · 40 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190100/> 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 May 16, 2026