

**K253314 Freedom Infinia™ Total Knee System**Oct 29, 2025  
29 days to decisionK253314 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k253314/>**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	Sep 30, 2025
Decision date	Oct 29, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maxx Orthopedics, Inc.</b>
Location	North Attleboro, MA, US
Contact	Corey Perine
510(k) history	23 submissions · 23 cleared · 2009-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Meril Healthcare Pvt. , Ltd.</b>
Contact	Bittu Jha

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253314/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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