

**K243295 Initia Knee System**Jan 13, 2025  
87 days to decisionK243295 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k243295/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Oct 18, 2024
Decision date	Jan 13, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kyocera Medical Technologies, Inc.</b>
Location	Redlands, CA, US
Contact	DeBenedictis Anthony
510(k) history	15 submissions · 15 cleared · 2020-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Swearingen Regulatory Consulting, LLC</b>
Contact	Audrey Swearingen

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

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