FDA 510(k) Premarket Notification

K243295 Initia Knee System

CLEARED

Jan 13, 2025
87 days to decision

K243295 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k243295/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Swearingen Regulatory Consulting, LLC**
Contact	Audrey Swearingen

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