FDA 510(k) Premarket Notification

K232114 TRIBRID® Unicompartmental Knee System

CLEARED

Apr 4, 2024
265 days to decision

K232114 · Product code: **HSX** · Orthopedic
Source: https://www.510kdatabase.net/k232114/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Jul 14, 2023
Decision date	Apr 4, 2024
Days to decision	265 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	Jason Lansdown
510(k) history	15 submissions · 15 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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