

K240863 Freedom® Total Knee SystemJul 2, 2024
96 days to decisionK240863 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k240863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Mar 28, 2024
Decision date	Jul 2, 2024
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Meril Healthcare Pvt. , Ltd.
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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