FDA 510(k) Premarket Notification

K251717 Freedom® Total Knee System – Titanium Tibial Base Plate

CLEARED

Jun 26, 2025
22 days to decision

K251717 · Product code: **JWH** · Orthopedic
Source: https://www.510kdatabase.net/k251717/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 4, 2025
Decision date	Jun 26, 2025
Days to decision	22 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