FDA 510(k) Premarket Notification

K240268 Accu-Joint Hemi Implant

CLEARED

Feb 29, 2024
29 days to decision

K240268 · Product code: **KWD** · Orthopedic
Source: https://www.510kdatabase.net/k240268/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	Jan 31, 2024
Decision date	Feb 29, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Accufix Surgical, Inc.**
Location	West Haven, CT, US
Contact	Michael Parisi
510(k) history	2 submissions · 2 cleared · 2020-2024

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