FDA 510(k) Premarket Notification

K223392 REVCON (TM) Screw System

CLEARED

Feb 28, 2023
112 days to decision

K223392 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k223392/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Nov 8, 2022
Decision date	Feb 28, 2023
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Voom Medical Devices, Inc.**
Location	New York City, NY, US
Contact	Neal M Blitz
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical**
Contact	Morgan Hill

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