FDA 510(k) Premarket Notification

K222799 Haymaker® Screw System

CLEARED

Jan 10, 2023
116 days to decision

K222799 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k222799/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 16, 2022
Decision date	Jan 10, 2023
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthocircle Spine D.B.A. OC Medical Devices**
Location	Savannah, GA, US
Contact	Jack Matthews
510(k) history	1 submissions · 1 cleared · 2023-2023

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