FDA 510(k) Premarket Notification

K222820 BRM TOOL Screws, BIOPLAN Subtalar Implant

CLEARED

Dec 16, 2022
88 days to decision

K222820 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k222820/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 19, 2022
Decision date	Dec 16, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brm Extremities**
Location	Milano, MI, US
Contact	Lisa Fazzini
510(k) history	2 submissions · 2 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Timothy Sutton

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