FDA 510(k) Premarket Notification

K220717 RedPoint Medical's Better Bunion System

CLEARED

Jun 9, 2022
90 days to decision

K220717 · Product code: **PBF** · Orthopedic
Source: https://www.510kdatabase.net/k220717/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Mar 11, 2022
Decision date	Jun 9, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Redpoint Medical, LLC**
Location	Carmel, IN, US
Contact	James Spitler
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert A. Poggie

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