FDA 510(k) Premarket Notification

K211076 Patient Specific Marking Guides

CLEARED

Jun 28, 2022
442 days to decision

K211076 · Product code: **PBF** · Orthopedic
Source: https://www.510kdatabase.net/k211076/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Apr 12, 2021
Decision date	Jun 28, 2022
Days to decision	442 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Additive Orthopaedics, LLC**
Location	Little Silver, NJ, US
Contact	Greg Kowalczyk
510(k) history	6 submissions · 6 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	**Paragon 28, Inc.**
Contact	Jan Triani

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