FDA 510(k) Premarket Notification

K221943 EmbedMed

CLEARED

Feb 1, 2023
211 days to decision

K221943 · Product code: **PBF** · Orthopedic
Source: https://www.510kdatabase.net/k221943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopaedic Surgical Planning And Instrument Guides (PBF)
Date received	Jul 5, 2022
Decision date	Feb 1, 2023
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3D Lifeprints UK , Ltd.**
Location	West Derby, Liverpool, Merseyside, GB
Contact	Henry Pinchbeck
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Olympus Regulatory Solutions**
Contact	Sam Murray

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