FDA 510(k) Premarket Notification

K220104 Knee+

CLEARED

Sep 1, 2022
232 days to decision

K220104 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k220104/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Jan 12, 2022
Decision date	Sep 1, 2022
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pixee Medical**
Location	Besan?on, FR
Contact	Lucie Pecheur
510(k) history	6 submissions · 6 cleared · 2021-2025