FDA 510(k) Premarket Notification

K233899 Knee+

CLEARED

Mar 8, 2024
88 days to decision

K233899 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k233899/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Dec 11, 2023
Decision date	Mar 8, 2024
Days to decision	88 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