FDA 510(k) Premarket Notification

K243975 Knee+

CLEARED

Mar 20, 2025
87 days to decision

K243975 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k243975/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Dec 23, 2024
Decision date	Mar 20, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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