FDA 510(k) Premarket Notification

K213922 FX SPS

CLEARED

Jul 22, 2022
219 days to decision

K213922 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k213922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 15, 2021
Decision date	Jul 22, 2022
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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