

**K213922 FX SPS**Jul 22, 2022  
219 days to decisionK213922 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k213922/>**SUBMISSION DETAILS**

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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**

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Company	<b>Pixee Medical</b>
Location	Besançon, FR
Contact	Agathe Joet
510(k) history	6 submissions · 6 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213922/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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