

**K230899 qXR-PTX-PE**Aug 22, 2023  
144 days to decisionK230899 · Product code: **QFM** · Radiology  
Source: <https://www.510kdatabase.net/k230899/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Mar 31, 2023
Decision date	Aug 22, 2023
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Qure.Ai Technologies</b>
Location	Mumbai, IN
Contact	Ayushi Mahendra
510(k) history	9 submissions · 9 cleared · 2020-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230899/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026