

K243171 Yushan X-Ray Flat Panel DetectorDec 19, 2024
80 days to decisionK243171 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k243171/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Sep 30, 2024
Decision date	Dec 19, 2024
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innocare Optoelectronics Corp.
Location	Tainan City, TW
Contact	April Cheng
510(k) history	6 submissions · 6 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243171/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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