

K213529 Focus HD 43 DetectorMar 29, 2022
145 days to decisionK213529 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k213529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Nov 4, 2021
Decision date	Mar 29, 2022
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Iray Technology Taicang , Ltd.
Location	Taicang, CN
Contact	Junjie Qian
510(k) history	21 submissions · 21 cleared · 2018-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213529/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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