

K183422 Wireless Digital Flat Panel DetectorJan 9, 2019
30 days to decisionK183422 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k183422/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Dec 10, 2018
Decision date	Jan 9, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183422/> Data sourced from FDA 510(k) public records (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. - Generated May 15, 2026