FDA 510(k) Premarket Notification

CLEARED

K201004 Wireless Digital Flat Panel Detector Model Name Mars1417V-TSI, Wireless Digital Flat Panel Detector Model Name Mano4336W

May 1, 2020
15 days to decision

K201004 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k201004/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Apr 16, 2020
Decision date	May 1, 2020
Days to decision	15 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.net
Device record: https://www.510kdatabase.net/k201004/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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