FDA 510(k) Premarket Notification

CLEARED

K212105 6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF

Aug 23, 2021
48 days to decision

K212105 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k212105/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jul 6, 2021
Decision date	Aug 23, 2021
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pzmedical Technology Co., Ltd.**
Location	Shanghai, CN
Contact	Peter Yixin Li
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov