FDA 510(k) Premarket Notification

K212051 RFA-1717DIG, RFA-1717DIC

CLEARED

Aug 25, 2021
56 days to decision

K212051 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k212051/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jun 30, 2021
Decision date	Aug 25, 2021
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Astel, Inc.**
Location	Daejeon, KR
Contact	Yonghwan Jeon
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Mtechgroup**
Contact	Dave Kim

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