

**K212051 RFA-1717DIG, RFA-1717DIC**Aug 25, 2021  
56 days to decisionK212051 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k212051/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtechgroup</b>
Contact	Dave Kim

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212051/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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