

**K211108 Prudent 1717, Prudent 1417, Prudent 1212**Jun 4, 2021  
51 days to decisionK211108 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k211108/>**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	Apr 14, 2021
Decision date	Jun 4, 2021
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pixxgen Corporation</b>
Location	Anyang-Si, KR
Contact	Young Kim
510(k) history	4 submissions · 4 cleared · 2018-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

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/k211108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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