

**K212134 Diagnostic X-ray System/PLX5200A**Aug 25, 2021  
48 days to decisionK212134 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k212134/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Jul 8, 2021
Decision date	Aug 25, 2021
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nanjing Perlove Medical Equipment Co., Ltd.</b>
Location	Nanjing, CN
Contact	Lu Fengfang
510(k) history	2 submissions · 2 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Landlink Healthcare Technology (Shanghai) Co., Ltd.</b>
Contact	Stuart Situ

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212134/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 25, 2026