

**K210312 PlutoX Digital Intraoral X-Ray Imaging System**Apr 23, 2021  
79 days to decisionK210312 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k210312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Feb 3, 2021
Decision date	Apr 23, 2021
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Iray Technology Taicang , Ltd.</b>
Location	Taicang, CN
Contact	Wei Pan
510(k) history	21 submissions · 21 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210312/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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