

K223010 Portable X-ray SystemJan 17, 2023
110 days to decisionK223010 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k223010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Sep 29, 2022
Decision date	Jan 17, 2023
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223010/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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