

**K230581 TOPA12 Portable X-ray Unit**Aug 16, 2023  
167 days to decisionK230581 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k230581/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Mar 2, 2023
Decision date	Aug 16, 2023
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neuf, Inc.</b>
Location	Jeollanam-Do, KR
Contact	Woo Sang Lee
510(k) history	2 submissions · 2 cleared · 2021-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>CTI Co., Ltd.</b>
Contact	Yeonwoo Lee

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

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