

K211383 NFLK-2501 Portable X-ray UnitAug 13, 2021
101 days to decisionK211383 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k211383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	May 4, 2021
Decision date	Aug 13, 2021
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Medmonts Co., Ltd.
Contact	Woo Sung Park

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

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