

K172928 Portable X-ray SystemMar 16, 2018
172 days to decisionK172928 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k172928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Sep 25, 2017
Decision date	Mar 16, 2018
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rolence Enterprise, Inc.
Location	Taoyuan, TW
Contact	Sterling Cheng
510(k) history	2 submissions · 2 cleared · 2018-2021

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