

K221587 DHX-70H, XTG-70HMar 3, 2023
275 days to decisionK221587 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k221587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jun 1, 2022
Decision date	Mar 3, 2023
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Digimed Co., Ltd.
Location	Seoul, KR
Contact	Youngbae Kwon
510(k) history	4 submissions · 4 cleared · 2018-2023

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