

K242591 XERO-alphaNov 1, 2024
63 days to decisionK242591 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k242591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Aug 30, 2024
Decision date	Nov 1, 2024
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DRTECH Corporation
Location	Seongam-Si, KR
Contact	Yeongsuk An
510(k) history	25 submissions · 25 cleared · 2015-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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