

K181891 Portable X-ray System (Model: MiniX-V, Mini X-S)Aug 10, 2018
28 days to decisionK181891 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k181891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 13, 2018
Decision date	Aug 10, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181891/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026