

K180561 MobileX Portable X-ray SystemApr 4, 2018
30 days to decisionK180561 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k180561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Mar 5, 2018
Decision date	Apr 4, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Denterprise International, Inc.
Location	Ormond Beach, FL, US
Contact	Claude Berthoin
510(k) history	4 submissions · 4 cleared · 2012-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180561/> 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 27, 2026