

**K092772 PORTABLE X-RAY SYSTEM, MODEL HAND-RAY**Jan 6, 2010  
119 days to decisionK092772 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k092772/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Sep 9, 2009
Decision date	Jan 6, 2010
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hanjin Digi-X Co., Ltd.</b>
Location	Salt Lake City, UT, US
Contact	SHIN KUK YOO
510(k) history	1 submissions · 1 cleared · 2010-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092772/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026