

**K113360 MEDICAL IMAGE PROCESSING UNIT**Feb 7, 2012  
85 days to decisionK113360 · Product code: **EAP** · Radiology  
Source: <https://www.510kdatabase.net/k113360/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, X-ray, Intraoral (EAP)
Date received	Nov 14, 2011
Decision date	Feb 7, 2012
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Humanray Co,Ltd</b>
Location	Houston, TX, US
Contact	DAVE KIM
510(k) history	2 submissions · 2 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113360/> 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