

**K100317 DIGITAL X-RAY IMAGING SYSTEM (PAX-PRIMO)  
MODEL PAX-PRIMO**Mar 24, 2010  
48 days to decisionK100317 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k100317/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Feb 4, 2010
Decision date	Mar 24, 2010
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>VATECH Co., Ltd.</b>
Location	Sound Beach, NY, US
Contact	DAVE KIM
510(k) history	39 submissions · 39 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100317/>; 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