

K130585 PCH-2500 DIGITAL EXTRAORAL SOURCE X-RAY SYSTEM, PAX-I DIGITAL EXTRAORAL SOURCE X-RAY SYSTEMJul 15, 2013
132 days to decisionK130585 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k130585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Mar 5, 2013
Decision date	Jul 15, 2013
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130585/> 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 17, 2026