FDA 510(k) Premarket Notification

K122155 PCH-2500 DIGITAL EXTRAORAL SOURCE X-RAY SYSTEM PAX-I DIGITAL EXTRAORAL SOURCE X-RAY SYSTEM

CLEARED

Sep 4, 2012
46 days to decision

K122155 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k122155/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jul 20, 2012
Decision date	Sep 4, 2012
Days to decision	46 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.net
Device record: https://www.510kdatabase.net/k122155/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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