

K222439 Atellica® CH Phencyclidine (Pcp), Atellica® CH Vancomycin (Vanc)Aug 8, 2023
361 days to decisionK222439 · Product code: LEH · Toxicology
Source: <https://www.510kdatabase.net/k222439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Aug 12, 2022
Decision date	Aug 8, 2023
Days to decision	361 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Joy Anoop
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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