FDA 510(k) Premarket Notification

K242170 K-ASSAY CRP (Ver.2)

CLEARED

Apr 18, 2025
268 days to decision

K242170 · Product code: **DCK** · Immunology
Source: https://www.510kdatabase.net/k242170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Jul 24, 2024
Decision date	Apr 18, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kamiya Biomedical Company, LLC**
Location	Tukwila, WA, US
Contact	Shawn Kaplan
Website	https://www.kamiya.com
510(k) history	1 submissions · 1 cleared · 2025-2025

Kamiya Biomedical Company, LLC develops and manufactures medical devices with a manufacturing facility in Tukwila, US. The company specializes in diagnostic and clinical laboratory solutions. The company has received FDA 510(k) clearances from total submissions. Kamiya Biomedical focuses exclusively on Immunology devices, with its first and latest clearance in 2025. This recent regulatory activity demonstrates the company's active status in the medical device market. Explore the company's cleared device names, product codes, and clearance dates in the database above.