FDA 510(k) Premarket Notification

K992312 K-ASSAY CRP (2), K-ASSAY CRP MULTI-CALIBRATOR A, K-ASSAY CRP MULTI-CALIBRATOR B

CLEARED

Sep 13, 1999
66 days to decision

K992312 · Product code: **DCK** · Immunology
Source: https://www.510kdatabase.net/k992312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Jul 9, 1999
Decision date	Sep 13, 1999
Days to decision	66 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Kamiya Biomedical Co.**
Location	Thousand Oaks, CA, US
Contact	COLIN GETTY
510(k) history	43 submissions · 43 cleared · 1991-2010