FDA 510(k) Premarket Notification

K972160 CRP-LEX SYSTEM: C-REACTIVE PROTEIN ANTIGEN DETECTION IN SERUM: SLIDE AGGLUTNATION LATEX TEST

CLEARED

Aug 1, 1997
53 days to decision

K972160 · Product code: **DCK** · Immunology
Source: https://www.510kdatabase.net/k972160/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Jun 9, 1997
Decision date	Aug 1, 1997
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Trinity Laboratories, Inc.**
Location	Raleigh, NC, US
Contact	BRUCE A CLINTON
510(k) history	44 submissions · 28 cleared · 1990-1998