K915320 RHEUMA-LEX(TM) SYST: RHEUMATOID FACTOR LATEX TEST

CLEARED

Dec 7, 1992
381 days to decision

K915320 · Product code: **DHR** · Immunology
Source: https://www.510kdatabase.net/k915320/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Nov 22, 1991
Decision date	Dec 7, 1992
Days to decision	381 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