K053603 C-REACTIVE PROTEIN (LATEX) HIGH SENSITIVE TEST SYSTEM FOR COBAS INTEGRA INSTRUMENTS

CLEARED

Feb 9, 2006
48 days to decision

K053603 · Product code: **NQD** · Chemistry
Source: https://www.510kdatabase.net/k053603/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cardiac C-reactive Protein, Antigen, Antiserum, And Control (NQD)
Date received	Dec 23, 2005
Decision date	Feb 9, 2006
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics Corp.**
Location	Indianapolis, IN, US
Contact	THERESA M AMBROSE
510(k) history	264 submissions · 263 cleared · 1999-2013