

K002651 C-REACTIVE PROTEIN (HIGH SENSITIVITY) REAGENT SETOct 13, 2000
49 days to decisionK002651 · Product code: **DCK** · Chemistry
Source: <https://www.510kdatabase.net/k002651/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Aug 25, 2000
Decision date	Oct 13, 2000
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pointe Scientific, Inc.,
Location	Mchenry, IL, US
Contact	RON JAMISON
510(k) history	74 submissions · 74 cleared · 1981-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002651/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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