

K050836 CRP DIAGNOSTIC ASSAYAug 8, 2005
129 days to decisionK050836 · Product code: **DCK** · Chemistry
Source: <https://www.510kdatabase.net/k050836/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Apr 1, 2005
Decision date	Aug 8, 2005
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sentinel Ch. Srl
Location	Rome, IT
Contact	Maria E Donawa
510(k) history	10 submissions · 10 cleared · 2005-2007

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