

K212559 CardioPhase® hsCRPDec 16, 2022
490 days to decisionK212559 · Product code: **NQD** · Chemistry
Source: <https://www.510kdatabase.net/k212559/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cardiac C-reactive Protein, Antigen, Antiserum, And Control (NQD)
Date received	Aug 13, 2021
Decision date	Dec 16, 2022
Days to decision	490 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics Products GmbH
Location	Marburg, DE
Contact	Martina Pfeiff
510(k) history	19 submissions · 18 cleared · 2016-2024

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