

K192072 Tina-quant C-Reactive Protein IVFeb 21, 2020
203 days to decisionK192072 · Product code: **DCN** · Immunology
Source: <https://www.510kdatabase.net/k192072/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, C-reactive Protein (DCN)
Date received	Aug 2, 2019
Decision date	Feb 21, 2020
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations (Rdo)
Location	Indianapolis, IN, US
Contact	Barbara Ann McWhorter
510(k) history	14 submissions · 14 cleared · 2014-2020

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