

K192028 Yumizen C1200 CRPJun 25, 2020
335 days to decisionK192028 · Product code: **DCK** · Immunology
Source: <https://www.510kdatabase.net/k192028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Jul 26, 2019
Decision date	Jun 25, 2020
Days to decision	335 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	HORIBA ABX SAS
Location	Montpellier Cedex 4, FR
Contact	Caroline Ferrer
510(k) history	17 submissions · 17 cleared · 2009-2024

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