

K193649 Yumizen C1200 Creatinine PAPMay 10, 2021
497 days to decisionK193649 · Product code: **JFY** · Chemistry
Source: <https://www.510kdatabase.net/k193649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Dec 30, 2019
Decision date	May 10, 2021
Days to decision	497 days
Third-party review	No
Combination product	No
PCCP authorized	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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