

K191396 Yumizen C1200 Calcium AS, Yumizen C1200 Creatinine JaffeJul 26, 2019
63 days to decisionK191396 · Product code: **CJY** · Chemistry
Source: <https://www.510kdatabase.net/k191396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Azo Dye, Calcium (CJY)
Date received	May 24, 2019
Decision date	Jul 26, 2019
Days to decision	63 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191396/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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