

K193525 Yumizen C1200 Immunoglobulin A, Yumizen C1200 Immunoglobulin G, Yumizen C1200 Immunoglobulin MJun 26, 2020
190 days to decisionK193525 · Product code: **CZP** · Immunology
Source: <https://www.510kdatabase.net/k193525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Iga, Antigen, Antiserum, Control (CZP)
Date received	Dec 19, 2019
Decision date	Jun 26, 2020
Days to decision	190 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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