

K214068 Quantia IgEFeb 21, 2023
421 days to decisionK214068 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k214068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Dec 27, 2021
Decision date	Feb 21, 2023
Days to decision	421 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biokit, S.A.
Location	Barcelona, ES
Contact	Angels Roma
510(k) history	23 submissions · 23 cleared · 2005-2025

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