

K221420 AlphaID™ At Home Genetic Health Risk ServiceOct 27, 2022
164 days to decisionK221420 · Product code: PTA · Immunology
Source: <https://www.510kdatabase.net/k221420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Genetic Variant Detection And Health Risk Assessment System (PTA)
Date received	May 16, 2022
Decision date	Oct 27, 2022
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Progenika Biopharma S.A., A Grifols Company
Location	Derio, ES
Contact	Diego Tejedor
510(k) history	4 submissions · 4 cleared · 2017-2022

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