

**K211115 A1AT Genotyping Test**May 13, 2021  
29 days to decisionK211115 · Product code: **PZH** · Immunology  
Source: <https://www.510kdatabase.net/k211115/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Serpina1 Variant Detection System (PZH)
Date received	Apr 14, 2021
Decision date	May 13, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211115/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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