

K213396 SPIFE A1AT kitOct 13, 2022
360 days to decisionK213396 · Product code: **OBZ** · Immunology
Source: <https://www.510kdatabase.net/k213396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-antitrypsin Kit, Qualitative Phenotype (OBZ)
Date received	Oct 18, 2021
Decision date	Oct 13, 2022
Days to decision	360 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Helena Laboratories, Corp.
Location	Beaumont, TX, US
Contact	Rachel Easley
510(k) history	2 submissions · 2 cleared · 2022-2022

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