

K211058 Lp(a) UltraDec 22, 2022
622 days to decisionK211058 · Product code: **DFC** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Apr 9, 2021
Decision date	Dec 22, 2022
Days to decision	622 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SENTINEL CH. SpA
Location	Milano, IT
Contact	Patricia Dupé
510(k) history	12 submissions · 12 cleared · 2007-2025

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