

K242585 Cystatin CMay 16, 2025
259 days to decisionK242585 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k242585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Aug 30, 2024
Decision date	May 16, 2025
Days to decision	259 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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