

**K063647 CYSTATIN C ANTISERUM, CALIBRATOR, CONTROL
AND CONTROL HIGH**Mar 12, 2007
95 days to decisionK063647 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k063647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Dec 7, 2006
Decision date	Mar 12, 2007
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thermo Electron OY
Location	Vantaa, FI
Contact	PAIVI SORMUNEN
510(k) history	9 submissions · 9 cleared · 2006-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063647/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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