

K100716 AUDIT MICROCV D-DIMER LINEARITY SET, MODEL K717M-5Jun 23, 2011
468 days to decisionK100716 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k100716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Mar 12, 2010
Decision date	Jun 23, 2011
Days to decision	468 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aalto Scientific, Ltd.
Location	Mchenry, IL, US
Contact	DESSI LYAKOV
510(k) history	35 submissions · 35 cleared · 1982-2017

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