

**K100715 AUDIT MICROCV HOMOCYSTEINE LINEARITY SET,  
MODEL 704M-5**

Dec 23, 2010  
286 days to decision

K100715 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k100715/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Mar 12, 2010
Decision date	Dec 23, 2010
Days to decision	286 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aalto Scientific, Ltd.</b>
Location	Mchenry, IL, US
Contact	BRANDON J PEREZ
510(k) history	35 submissions · 35 cleared · 1982-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k100715/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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