

**K981978 AUTOLDL CHOLESTEROL REAGENT SET AND  
AUTOLDL CHOLESTEROL CALIBRATOR**

Jul 22, 1998  
47 days to decision

K981978 · Product code: MRR · Chemistry  
Source: <https://www.510kdatabase.net/k981978/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Jun 5, 1998
Decision date	Jul 22, 1998
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pointe Scientific, Inc.,</b>
Location	Mchenry, IL, US
Contact	WILLIAM F WALTERS, JR.
510(k) history	74 submissions · 74 cleared · 1981-2007

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

Device record: <https://www.510kdatabase.net/k981978/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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