

**K982767 RAICHEM HDL-CHOLESTEROL DIRECT REAGENT,  
HDL-CHOLESTEROL CALIBRATOR**Sep 21, 1998  
46 days to decisionK982767 · Product code: JIX · Chemistry  
Source: <https://www.510kdatabase.net/k982767/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Aug 6, 1998
Decision date	Sep 21, 1998
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Raichem</b>
Location	San Diego, CA, US
Contact	MELISSA SANER
510(k) history	1 submissions · 1 cleared · 1998-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982767/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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