

**K991083 RLP CHOLESTEROL IMMUNOSEPARATION ASSAY**Aug 20, 1999  
142 days to decisionK991083 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k991083/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Mar 31, 1999
Decision date	Aug 20, 1999
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Otsuka Pharmaceutical Co., Ltd.</b>
Location	Rockville, MD, US
Contact	JAMES W HARRIS
Website	<a href="http://www.otsuka.co.jp">http://www.otsuka.co.jp</a>
510(k) history	6 submissions · 6 cleared · 1999-2010

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