

K001032 RLP-CHOLESTEROL IMMUNOSEPARATION ASSAYJul 24, 2000
116 days to decisionK001032 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k001032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Mar 30, 2000
Decision date	Jul 24, 2000
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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