

K980812 IMX HOMOCYSTEINEOct 1, 1998
212 days to decisionK980812 · Product code: **DFC** · Chemistry
Source: <https://www.510kdatabase.net/k980812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Mar 3, 1998
Decision date	Oct 1, 1998
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis Biochemicals, Asa
Location	San Diego, CA, US
Contact	RONALD G LEONARDI, PH.D.
510(k) history	3 submissions · 3 cleared · 1998-1999

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