

K981478 ACS:CENTAUR CEAAug 12, 1998
110 days to decisionK981478 · Product code: **DHX** · Immunology
Source: <https://www.510kdatabase.net/k981478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Apr 24, 1998
Decision date	Aug 12, 1998
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chiron Diagnostics Corp.
Location	Medfield, MA, US
Contact	THOMAS F FLYNN
510(k) history	20 submissions · 20 cleared · 1997-1999

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