

K080194 VIDAS CEA (S) ASSAYOct 9, 2008
258 days to decisionK080194 · Product code: **DHX** · Immunology
Source: <https://www.510kdatabase.net/k080194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Jan 25, 2008
Decision date	Oct 9, 2008
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	NIKITA S MAPP
510(k) history	251 submissions · 250 cleared · 1983-2026

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