FDA 510(k) Premarket Notification

K031270 ACCESS CEA REAGENTS FOR USE ON THE ACCESS IMMUNOASSAY SYSTEMS

CLEARED

May 6, 2003
15 days to decision

K031270 · Product code: **DHX** · Immunology
Source: https://www.510kdatabase.net/k031270/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Apr 21, 2003
Decision date	May 6, 2003
Days to decision	15 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	LYNN WEIST
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...