

K914486 COULTER CARBON DIOXIDE REAGENTNov 27, 1991
50 days to decisionK914486 · Product code: **KHS** · Chemistry
Source: <https://www.510kdatabase.net/k914486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic, Carbon-dioxide (KHS)
Date received	Oct 8, 1991
Decision date	Nov 27, 1991
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Coulter Corp.
Location	Hialeah, FL, US
Contact	JIM HOSKINSON
510(k) history	51 submissions · 51 cleared · 1989-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914486/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026