

K954755 COAT-A-COUNT DIRECT ANDROSTENEDIONENov 29, 1995
44 days to decisionK954755 · Product code: **CIZ** · Chemistry
Source: <https://www.510kdatabase.net/k954755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Androstenedione (CIZ)
Date received	Oct 16, 1995
Decision date	Nov 29, 1995
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Products Corp.
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE
510(k) history	321 submissions · 321 cleared · 1976-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954755/> 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 20, 2026