

K943098 HUMAN IGG SUBCLASSES ELISA COMBI KITSep 7, 1994
71 days to decisionK943098 · Product code: **DAS** · Immunology
Source: <https://www.510kdatabase.net/k943098/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg (fc Fragment Specific), Antigen, Antiserum, Control (DAS)
Date received	Jun 28, 1994
Decision date	Sep 7, 1994
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Research Diagnostics, Inc.
Location	Flanders, NJ, US
Contact	BRET WIEN
510(k) history	3 submissions · 3 cleared · 1994-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943098/> 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 30, 2026